

Using nano diamond knives is the most economical way to perform a clear corneal or a side-port

incision. Get a diamond scalpel at the price of a sapphire knife.



# sharpness at its peak

## Nano Diamond knives Made in Switzerland

## Amidia AG

Amidia AG has been manufacturing diamond knives for ophthalmology, micro surgery and plastic surgery for the last 20 years. Our many years of experience and strict quality control allows us to only manufacture and sell firstclass products.

Since 2015 Amidia offers the unique Nano Diamond Blades. These reusable knives are a perfect alternative to single-use knives. If handled correctly more than 1000 surgeries per knife are possible. Thereby the cost can be cut down and less waste conserves the environment.

In the area of ophthalmology, we offer all commonly used designs. Inquiries for new blade types/dimensions will be gladly considered and realized, if possible.

### **IMPORTANT:**

We also resharpen and maintain diamond knives of other manufacturers.

Feel free to contact us with all questions regarding our high-quality products. We would be happy to assist you any time.

Amidia AG



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### Facts about nano diamond knives

- Nano Diamond blades are the sharpest scalpels available.
- · Nano Diamond blades never get dull only damaged by improper use!
- Nano Diamond blades are the most economical cutting instruments available.

### How long does a nano diamond blade last?

Since a nano diamond blade cannot get dull, it lasts theoretically forever. The blade gets damaged only if it touches an instrument, another hard object or if it falls to the floor.

We suggest sending Nano diamond knives for inspection to our company at least after 500 surgeries.



## Nano diamond knives summary



## Nano diamond knives with single edge

with an anodized handle

with an aluminium handle



| Article     | Articlo Total |          | ndle      | Mou      | nting  | Thick | kness | Length | Angle | Width  |        |
|-------------|---------------|----------|-----------|----------|--------|-------|-------|--------|-------|--------|--------|
| Article     | TUTAL         | Anodized | Aluminium | Straight | Angled | 100um | 150um | 3.50mm | 45°   | 1.00mm | 1.50mm |
| Single edge | 9             | 6        | 3         | 6        | 3      | 3     | 6     | 9      | 9     | 6      | 3      |



### Single edge with an anodized handle

| single | edge 45° |
|--------|----------|
|--------|----------|

|   |            |               |           | angled mounting | straight mounting |
|---|------------|---------------|-----------|-----------------|-------------------|
| width (w)   | length (I) | thickness (t) | angle (a) | order no.       | order no.         |
| 1.00 mm   | 3.50 mm    | 0.15mm        | 45°       | A-nano-C1000A   | A-nano-C1000      |
|   |            |               |           |                 |                   |
| 1.50 mm   | 3.50 mm    | 0.15mm        | 45°       |                 | A-nano-C1005      |
| Ultra Sharp Series<br>blade thickness 100 micron on | ly         |               |           |                 |                   |
| 1.00 mm   | 3.50 mm    | 0.10mm        | 45°       | A-nano-SC1000A  | A-nano-SC1000     |
|   |            |               |           |                 |                   |
| 1.50 mm   | 3.50 mm    | 0.10mm        | 45°       |                 | A-nano-SC1005     |

### Single edge with an alumium handle

| single edge 45° |            |               |           |                 |                   |  |  |
|-----------------|------------|---------------|-----------|-----------------|-------------------|--|--|
|                 |            |               |           | angled mounting | straight mounting |  |  |
| width (w)       | length (l) | thickness (t) | angle (a) | order no.       | order no.         |  |  |
| 1.00 mm         | 3.50 mm    | 0.15mm        | 45°       | A-nano-UB1000A  | A-nano-UB1000     |  |  |
| 1.50 mm         | 3.50 mm    | 0.15mm        | 45°       |                 | A-nano-UB1005     |  |  |



## Nano diamond knives with clear cornea

### with an anodized handle

|  | with an alumium handle |
|--|------------------------|
| Highlights:  | with an plastic handle |
| <ul> <li>Nano diamond<br/>knives are the perfect<br/>alternative to disposable<br/>knives</li> <li>now also available with<br/>100 micron blades<br/>(Ultra Sharp Series)</li> </ul> |                        |

| Article      |         | Handle   |           | Mounting type | Thick | mess  | Length | Angle | Width  |        |        |        |        |        |        |        |        |        |
|--------------|---------|----------|-----------|---------------|-------|-------|--------|-------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|
|              | Plastic | Anodized | Aluminium | Angled        | 100um | 150um | 4.00mm | 70°   | 1.80mm | 2.20mm | 2.40mm | 2.50mm | 2.60mm | 2.65mm | 2.75mm | 2.80mm | 3.00mm | 3.20mm |
| Clear Cornea | 9       | 20       | 10        | 9             | 10    | 29    | 39     | 39    | 3      | 4      | 4      | 4      | 4      | 4      | 4      | 4      | 4      | 4      |



### Clear Cornea with an anodized handle

| angled mountin | g                     |               |                    |                            |
|----------------|-----------------------|---------------|--------------------|----------------------------|
| width (w)      | length (I)            | thickness (t) | angle (a)          | order no.                  |
| 1.80 mm        | 4.00 mm               | 0.15 mm       | 70°                | A-nano-C1123A              |
| 2.20 mm        | 4.00 mm               | 0.15 mm       | 70°                | A-nano-C1127A              |
| 2.40 mm        | 4.00 mm               | 0.15 mm       | 70°                | A-nano-C1129A              |
| 2.50 mm        | 4.00 mm               | 0.15 mm       | 70°                | A-nano-C1130A              |
| 2.60 mm        | 4.00 mm               | 0.15 mm       | 70°                | A-nano-C1131A              |
| 2.65 mm        | 4.00 mm               | 0.15 mm       | 70°                | A-nano-C1132A              |
| 2.75 mm        | 4.00 mm               | 0.15 mm       | 70°                | A-nano-C1132-01A           |
| 2.80 mm        | 4.00 mm               | 0.15 mm       | 70°                | A-nano-C1133A              |
| 3.00 mm        | 4.00 mm               | 0.15 mm       | 70°                | A-nano-C1135A              |
| 3.20 mm        | 4.00 mm               | 0.15 mm       | 70°                | A-nano-C1137A              |
| ULTRA SHARP Ve | rsion - with a 100 mi | cron blade    |                    | 105                        |
| 1.80 mm        | 4.00 mm               | 0.10 mm       | 70° Illtra Shar    | p Series on Annano-SC1123A |
| 2.20 mm        | 4.00 mm               | 0.10 mm       | 70° blade thicknes | A-nano-SC1127A             |
| 2.40 mm        | 4.00 mm               | 0.10 mm       | 70°                | A-nano-SC1129A             |
| 2.50 mm        | 4.00 mm               | 0.10 mm       | 70°                | A-nano-SC1130A             |
| 2.60 mm        | 4.00 mm               | 0.10 mm       | 70°                | A-nano-SC1131A             |
| 2.65 mm        | 4.00 mm               | 0.10 mm       | 70°                | A-nano-SC1132A             |
| 2.75 mm        | 4.00 mm               | 0.10 mm       | 70°                | A-nano-SC1132-01A          |
| 2.80 mm        | 4.00 mm               | 0.10 mm       | 70°                | A-nano-SC1133A             |
| 3.00 mm        | 4.00 mm               | 0.10 mm       | 70°                | A-nano-SC1135A             |
| 3.20 mm        | 4.00 mm               | 0.10 mm       | 70°                | A-nano-SC1137A             |



## Nano diamond knives with clear cornea

with an anodized handle

|  |            | with an alumium handle |
|--|------------|------------------------|
| Highlights:  |            | with an plastic handle |
| <ul> <li>Nano diamond<br/>knives are the perfect<br/>alternative to disposable<br/>knives</li> <li>now also available with<br/>100 micron blades<br/>(Ultra Sharp Series)</li> </ul> | 118mm ±2.0 |                        |

| Article      |         | Handle   |           | Mounting type | Thick | mess  | Length | Angle | Width  |        |        |        |        |        |        |        |        |        |
|--------------|---------|----------|-----------|---------------|-------|-------|--------|-------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|
|              | Plastic | Anodized | Aluminium | Angled        | 100um | 150um | 4.00mm | 70°   | 1.80mm | 2.20mm | 2.40mm | 2.50mm | 2.60mm | 2.65mm | 2.75mm | 2.80mm | 3.00mm | 3.20mm |
| Clear Cornea | 9       | 20       | 10        | 9             | 10    | 29    | 39     | 39    | 3      | 4      | 4      | 4      | 4      | 4      | 4      | 4      | 4      | 4      |



### Clear Cornea with an aluminium handle

| angled mountin | g          |               |           |                   |
|----------------|------------|---------------|-----------|-------------------|
| width (w)      | length (l) | thickness (t) | angle (a) | order no.         |
| 1.80 mm        | 4.00 mm    | 0.15 mm       | 70°       | A-nano-UB1123A    |
| 2.20 mm        | 4.00 mm    | 0.15 mm       | 70°       | A-nano-UB1127A    |
| 2.40 mm        | 4.00 mm    | 0.15 mm       | 70°       | A-nano-UB1129A    |
| 2.50 mm        | 4.00 mm    | 0.15 mm       | 70°       | A-nano-UB1130A    |
| 2.60 mm        | 4.00 mm    | 0.15 mm       | 70°       | A-nano-UB1131A    |
| 2.65 mm        | 4.00 mm    | 0.15 mm       | 70°       | A-nano-UB1132A    |
| 2.75 mm        | 4.00 mm    | 0.15 mm       | 70°       | A-nano-UB1132-01A |
| 2.80 mm        | 4.00 mm    | 0.15 mm       | 70°       | A-nano-UB1133A    |
| 3.00 mm        | 4.00 mm    | 0.15 mm       | 70°       | A-nano-UB1135A    |
| 3.20 mm        | 4.00 mm    | 0.15 mm       | 70°       | A-nano-UB1137A    |

## Nano diamond knives with clear cornea

with an anodized handle

with an alumium handle

with an plastic handle

### Highlights:

 Nano diamond knives are the perfect alternative to disposable knives

| amond       |               |
|-------------|---------------|
| re the per- | • 137mm ±2.0• |
| rnative to  |               |
| ble knives  |               |
|             |               |
|             |               |
|             |               |
|             |               |

Econo verison

| Article      | Handle Mounting |          |           | Mounting type | Thick | Thickness Length Angle Width |        |     |        |        |        |        |        |        |        |        |        |        |
|--------------|-----------------|----------|-----------|---------------|-------|------------------------------|--------|-----|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|
|              | Plastic         | Anodized | Aluminium | Angled        | 100um | 150um                        | 4.00mm | 70° | 1.80mm | 2.20mm | 2.40mm | 2.50mm | 2.60mm | 2.65mm | 2.75mm | 2.80mm | 3.00mm | 3.20mm |
| Clear Cornea | 9               | 20       | 10        | 9             | 10    | 29                           | 39     | 39  | 3      | 4      | 4      | 4      | 4      | 4      | 4      | 4      | 4      | 4      |



### Clear Cornea with an plastic handle

| angled mountin | g          |               |           |                   |
|----------------|------------|---------------|-----------|-------------------|
| width (w)      | length (I) | thickness (t) | angle (a) | order no.         |
| 2.20 mm        | 4.00 mm    | 0.15 mm       | 70°       | A-nano-PL1127A    |
| 2.40 mm        | 4.00 mm    | 0.15 mm       | 70°       | A-nano-PL1129A    |
| 2.50 mm        | 4.00 mm    | 0.15 mm       | 70°       | A-nano-PL1130A    |
| 2.60 mm        | 4.00 mm    | 0.15 mm       | 70°       | A-nano-PL1131A    |
| 2.65 mm        | 4.00 mm    | 0.15 mm       | 70°       | A-nano-PL1132A    |
| 2.75 mm        | 4.00 mm    | 0.15 mm       | 70°       | A-nano-PL1132-01A |
| 2.80 mm        | 4.00 mm    | 0.15 mm       | 70°       | A-nano-PL1133A    |
| 3.00 mm        | 4.00 mm    | 0.15 mm       | 70°       | A-nano-PL1135A    |
| 3.20 mm        | 4.00 mm    | 0.15 mm       | 70°       | A-nano-PL1137A    |
|                |            |               |           |                   |

## 

## Nano diamond knives with lance

### with an anodized handle

with an alumium handle

with an plastic handle

angled mounting

straight mounting

### - 118mm ±2.0 -Highlights: - Nano diamond knives are the perfect alternative to disposable knives 117mm ±2.0 -- now also available with 100 micron blades (Ultra Sharp Series)

| Article | Total |         | Handle   |           | Mounting type Thicknes |        | mess  | Length Angle |        | Width |     |     |        |        |        |        |
|---------|-------|---------|----------|-----------|------------------------|--------|-------|--------------|--------|-------|-----|-----|--------|--------|--------|--------|
| Anticle |       | Plastic | Anodized | Aluminium | Straight               | Angled | 100um | 150um        | 3.50mm | 30°   | 60° | 70° | 0.80mm | 0.90mm | 1.00mm | 1.50mm |
| Lance   | 18    | 6       | 8        | 4         | 12                     | 6      | 4     | 14           | 18     | 12    | 3   | 3   | 2      | 2      | 13     | 1      |



### Lance with an anodized handle

| Lance with an   | anouized nand | lie           |           | angled mounting | straight mounting |
|---|---------------|---------------|-----------|-----------------|-------------------|
| width (w)   | length (I)    | thickness (t) | angle (a) | order no.       | order no.         |
| 1.00 mm   | 3.50 mm       | 0.15mm        | 30°       | A-nano-C1100A   | A-nano-C1100      |
|   |               |               |           |                 |                   |
| 1.00 mm   | 3.50 mm       | 0.15mm        | 60°       |                 | A-nano-C1110      |
|   |               |               |           |                 |                   |
| 1.00 mm   | 3.50 mm       | 0.15mm        | 70°       |                 | A-nano-C1120      |
| Ultra Sharp Series<br>blade thickness 100 micron only |               |               |           |                 |                   |
| 1.00 mm   | 3.50 mm       | 0.10mm        | 30°       | A-nano-SC1100A  | A-nano-SC1100     |
| 1.00 mm   | 3.50 mm       | 0.10mm        | 60°       |                 | A-nano-SC1110     |
|   |               |               |           |                 |                   |
| 1.00 mm   | 3.50 mm       | 0.10mm        | 70°       |                 | A-nano-SC1120     |

### Lance with an aluminium handle

|           |            |               |           | angioa mounting | otrangine mountaing |
|-----------|------------|---------------|-----------|-----------------|---------------------|
| width (w) | length (I) | thickness (t) | angle (a) | order no.       | order no.           |
| 1.00 mm   | 3.50 mm    | 0.15mm        | 30°       | A-nano-UB1100A  | A-nano-UB1100       |
|           |            |               |           |                 |                     |
| 1.00 mm   | 3.50 mm    | 0.15mm        | 60°       |                 | A-nano-UB1110       |
|           |            |               |           |                 |                     |
| 1.50 mm   | 3.50 mm    | 0.15mm        | 70°       |                 | A-nano-UB1120       |
|           |            |               |           |                 |                     |

### Lance with an plastic handle

|           | plastic nativie | angled mounting | straight mounting |                |               |
|-----------|-----------------|-----------------|-------------------|----------------|---------------|
| width (w) | length (l)      | thickness (t)   | angle (a)         | order no.      | order no.     |
| 0.80 mm   | 3.50 mm         | 0.15mm          | 30°               | A-nano-PL1090A | A-nano-PL1090 |
|           |                 |                 |                   |                |               |
| 0.90 mm   | 3.50 mm         | 0.15mm          | 30°               | A-nano-PL1095A | A-nano-PL1095 |
|           |                 |                 |                   |                |               |
| 1.00 mm   | 3.50 mm         | 0.15mm          | 30°               | A-nano-PL1100A | A-nano-PL1100 |



## Nano diamond knives with crescent

### with an anodized handle

| with  | on  | alun  | aium   | handla   |  |
|-------|-----|-------|--------|----------|--|
| WILII | all | diuli | IIUIII | liallule |  |

| Highlights:  |                | with an plastic handle |
|--|----------------|------------------------|
| <ul> <li>Nano diamond<br/>knives are the perfect<br/>alternative to disposable<br/>knives</li> <li>now also available with<br/>100 micron blades<br/>(Ultra Sharp Series)</li> </ul> | • 118mm ±2.0 — |                        |

| Articlo  | Total | Handle  |          | Mounting type | Thickness |       | Length | Angle  | Wi | dth    |        |
|----------|-------|---------|----------|---------------|-----------|-------|--------|--------|----|--------|--------|
| Article  |       | Plastic | Anodized | Aluminium     | Angled    | 100um | 150um  | 4.00mm | NA | 1.40mm | 2.00mm |
| Crescent | 8     | 2       | 4        | 2             | 8         | 2     | 6      | 8      | 8  | 4      | 4      |



### Crescent with an anodized handle

| angled mounting                                       |            |               |           |                |
|---|------------|---------------|-----------|----------------|
| width (w)   | length (I) | thickness (t) | angle (a) | order no.      |
| 1.40 mm   | 4.00 mm    | 0.15 mm       |           | A-nano-C1302A  |
| 2.00 mm   | 4.00 mm    | 0.15 mm       |           | A-nano-C1306A  |
| Ultra Sharp Series<br>blade thickness 100 micron only |            |               |           |                |
| 1.40 mm   | 4.00 mm    | 0.10 mm       |           | A-nano-SC1302A |
| 2.00 mm   | 4.00 mm    | 0.10 mm       |           | A-nano-SC1306A |

### Crescent with an aluminium handle

| angled mounting |            |               |           |                |  |  |  |  |  |
|-----------------|------------|---------------|-----------|----------------|--|--|--|--|--|
| width (w)       | length (l) | thickness (t) | angle (a) | order no.      |  |  |  |  |  |
| 1.40 mm         | 4.00 mm    | 0.15 mm       |           | A-nano-UB1302A |  |  |  |  |  |
| 2.00 mm         | 4.00 mm    | 0.15 mm       |           | A-nano-UB1306A |  |  |  |  |  |

### Crescent with an plastic handle

### angled mounting

| width (w) | length (I) | thickness (t) | angle (a) | order no.      |
|-----------|------------|---------------|-----------|----------------|
| 1.40 mm   | 4.00 mm    | 0.15 mm       |           | A-nano-PL1302A |
| 2.00 mm   | 4.00 mm    | 0.15 mm       |           | A-nano-PL1306A |

## Nano diamond knives with tri-facet

### with an anodized handle

with an aluminium handle



| Article   | Total | H        | Handle Mounting type |          | Thickness |       | Length | Angle  | Width   |        |
|-----------|-------|----------|----------------------|----------|-----------|-------|--------|--------|---------|--------|
|           |       | Anodized | Aluminium            | Straight | Angled    | 100um | 150um  | 3.50mm | 30°/30° | 1.00mm |
| Tri-facet | 6     | 4        | 2                    | 3        | 3         | 2     | 4      | 6      | 6       | 6      |



### Tri-facet with an anodized handle

|   |  |            |               |           | angled mounting | straight mounting |
|---|--|------------|---------------|-----------|-----------------|-------------------|
| ٧ | vidth (w)  | length (I) | thickness (t) | angle (a) | order no.       | order no.         |
|   | 1.00 mm  | 3.50 mm    | 0.15mm        | 30°/30°   | A-nano-C1200A   | A-nano-C1200      |
|   | Ultra Sharp Series<br>blade thickness 100 micron onl | y          |               |           |                 |                   |
|   | 1.00 mm  | 3.50 mm    | 0.10mm        | 30°/30°   | A-nano-SC1200A  | A-nano-SC1200     |

### Tri-facet with an alumium handle

|           |            |               |           | angled mounting | straight mounting |
|-----------|------------|---------------|-----------|-----------------|-------------------|
| width (w) | length (I) | thickness (t) | angle (a) | order no.       | order no.         |
| 1.00 mm   | 3.50 mm    | 0.15mm        | 30/30°    | A-nano-UB1200A  | A-nano-UB1200     |



### Instructions for use

### Amidia Nano-diamond scalpels

Legend to Symbols:

| Manufacturer | Article<br>Number | Unsterile      | Directions for use to<br>consider | Attention   | CE<br>Klasse I | CE Klasse Im   |
|--------------|-------------------|----------------|-----------------------------------|-------------|----------------|----------------|
|              | REF               | NON<br>STERILE | Ĩ                                 | $\triangle$ | CE             | <b>CE</b> 1250 |

### Description

Diamond scalpels are reusable instruments, consisting of a handle and a diamond blade. The blades are made from synthetic nano diamond and measure between 100µm and 200µm thick; the handles are made from plastic or aluminium.

### Applications

Diamond scalpels are designed for various microsurgery incisions.

### Precautions

- Read instructions before use
- Diamond scalpels are not sterile and must be sterilised.

#### Instructions for use

- Diamond scalpels must be thoroughly cleaned and sterilised before use. Diamond scalpels must also be cleaned and then sterilised after every subsequent use. For instructions on how to clean and sterilise diamond scalpels please refer to the section entitled **Cleaning and Sterilisation.**
- The diamond blades must never come into contact with other instruments. Special care must therefore be taken during surgical operations, to ensure that the blades do not come into contact with instruments such as forceps/tweezers or sharp surgical instruments.
- Ensure that diamond blades are not damaged before use. Damaged diamond scalpels should not be used. After every use of a diamond scalpel, care must be taken to ensure that the blade is protected by the protection cap.

### Cleaning

The machine cleaning process and the manual cleaning process were performed and validated by the company SMP GmbH, D-72072 Tübingen, Germany.

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| Ontor    | u   |

| No. | Criterion  | Acceptance<br>level      | References  |
|-----|--|--------------------------|---|
| 1   | There shall be no soil visible on the sample at the end of the cleaning process. | N/A                      | EN ISO 15883-1:2014 / RKI guideline: 2012<br>AAMI TIR 30: 2011 /Guideline DGKH, DGSV, AKI: 2014                         |
| 2   | The total amount of protein per sample shall be                                  | <100 µg                  | RKI guideline: 2012   |
| 3   | The total amount of protein per sample shall be                                  | < 200 µg                 | EN ISO 15883-1:2014   |
| 4   | The amount of protein/cm <sup>2</sup> shall be                                   | < 6.4 µg/cm <sup>2</sup> | AAMI TIR 30: 2011 Alfa et al AJIC<br>1999   |
| 5   | The amount of protein/cm <sup>2</sup> shall be                                   | < 3.0 µg/cm <sup>2</sup> | Guideline DGKH, DGSV, AKI: 2014   |
| 6   | The amount of hemoglobin/cm <sup>2</sup> shall be                                | < 2.2 µg/cm <sup>2</sup> | AAMI TIR 30: 2011 Alfa et al AJIC<br>1999   |
| 7   | The total amount of radioactivity per sample shall be                            | < 5 cps                  | SMP Report 11011010605:<br>Validation of the acceptance criteria of the Radionuclide<br>Method as performed by SMP GmbH |



### **Machine cleaning**

#### Machine Cleaning:

Use the following program for automated cleaning:

- ensure that each blade is retracted into the handle
- place the knives in a metal tray and secure them by silicone brackets. See picture below.
- 2 min pre-cleaning with cold tap water
- 5 min cleaning with 55° tap water and 0.5% cleaning solution neodisher Mediclean forte (Dr. Weigert, D-Hamburg) or comparable
- draining
- 3 min rinsing with cold deionized water
- draining
- 2 min rinsing with cold deionized water
- draining



#### Note:

- During the entire automated cleaning process the blade is retracted in the handle.
- Washer-disinfector: Miele Professional G 7836 CD or a similar Washer-disinfector are recommended.

### Manual cleaning

- 1. Brush the handle of the knife under running cold tap water with a soft nylon brush until it's visibly clean. The blade has to be retracted into the handle.
- 2. Extend the blade and rinse the blade under running cold tap water for 10s or until all visible soil is removed. Do not touch the blade with another object.
- 3. Place the knife (with the blade retracted in the handle) in a 0.5% cleaning solution of Neodisher Mediclean Forte (Dr. Weigert, D-Hamburg) or comparable at room temperature (20°C ± 2°C) for 10 minutes.
- 4. Rinse the knife under running deionized water (room temperature 20°C ± 2°C) for 1 minute

### Note:

### The diamond blades must <u>never</u> come into contact with other instruments; otherwise there is a risk that the blades will be damaged. Great care must therefore be taken when loading washing machines.

After cleaning, the condition of the instrument must be checked. Visually inspect the blade to ensure that it is not broken. Following this, the diamond scalpel must be immediately placed in the sterilisation box or in another suitable container. **Do not clean** diamond scalpels in ultra-sound cleaning systems.



### Sterilization

- Diamond scalpels <u>must</u> be sterilised before each use.
- Diamond scalpels must be sterilised with the diamond blades retracted. Please therefore ensure that the blade is protected.

| Sterilization method | Type of sterilization     | Item loaded    | Temperature   | Sterilization time |
|----------------------|---------------------------|----------------|---------------|--------------------|
| Steam                | Gravity Displacement Mode | Double wrapped | 132°C (270°F) | 15 minutes         |
| Steam                | Pre-vacuum Mode           | Double wrapped | 132°C (270°F) | 4 minutes          |

The validation of the sterilization behaviour was examined and validated according to EM ISO 14937.

#### Note:

- Diamond blades are made from an extremely hard but sensitive material. Handle these ultra-sharp blades carefully to avoid damage.
- Mechanical contact **must** be prevented.
- Diamond scalpels must be cleaned and sterilised before each use.
- After use the blade must be immediately protected by the protection cap.
- Diamond scalpels must <u>never</u> be stored un-cleaned.

#### Maintenance / Guarantee

The manufacturer does not grant any warranty, neither on the blade nor on the handle.

### **Proper Disposal**

The country specific laws and regulations have to be observed for proper disposal.

Manufacturer: Amidia AG Mattenstrasse 11 CH-2555 Brügg

## Why diamonds are better than disposable blades

We conducted a retrospective study of 12,182 consecutive patients who underwent clear corneal phacoemulsification, comparing incision technologies.

### Group A

In 3,912 patients the main and sideport incisions were created with diamonds.

Group B In 8,270 patients standard metal keratomes were employed for both incisions.

All patients were seen within 8 hours of surgery. There were no postoperative wound leaks (0/3,912) at any point in time with a mean first visit postoperative pressure of 19.2 mm Hg in Group A.

There were 9/8,270 (p<0.05) wound leaks with a mean first visit postoperative pressure of 21.6 mm Hg (p<0.05) in Group B. All 9 wound leaks in Group B were from the sideport. 3/9 wound leaks required suturing. 6/9 wound leaks sealed spontaneously. The intraocular pressure difference reflected the need to hydrate the wounds more in Group B as they were more difficult to seal and the eyes were left with a higher intraocular pressure at the end of the case. 180/3,912 (4.55%) of patients in Group A had an early IOP spike greater than 28 mm Hg versus 842/8,270 (10.18%) in Group B (p<0.05).

None of the patients in either group experienced an endophthalmitis or vascular occlusion.

We found that the use of diamonds for the incision significantly reduced the rate of wound leaks and the amount of wound hydration resulting in lower early postoperative IOP's and potentially dangerous IOP spikes.

Christoph Kranemann, MD



### Performance / sharpness

orce (mN)

- The sharpness / performance of Nano Diamond knifes is adjusted to match the penetration performance of diamond knifes.
- The shape of the penetration force curve is engineered to give an adequate tactile feedback and comfortable control of the knife to the surgeon.
- Undesired peak effects have been corrected by special tip shape designs.
- For development and quality insurance reasons, the sharpness of our blades is measured by a force vs. dislocation test, penetrating a plastic foil.





## Performance / sharpness

- Nano diamond blades are adjusted to match the maximum penetration force of best MKD/CVD Diamond blades.
- Phase 2 forces remain almost constant for Nano diamond blades, due to concave shaped tip design.







### General

- Batch process, cost efficient and highly reproducible .
- Wafer process cost determines pricing, independent from geometry.
- No mechanical grinding involved .
- No dull edges possible / sharpness always at physical limit
- Cutting edge formed from artificial diamond (hardest material).
- Reusable product (up to 1000 surgeries per scalpel proven)
- Lifetime not limited by no. of cuts nor sterilization cycles
- Patented product







For more information about our service, please contact your distributor in China or Amidia AG.

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