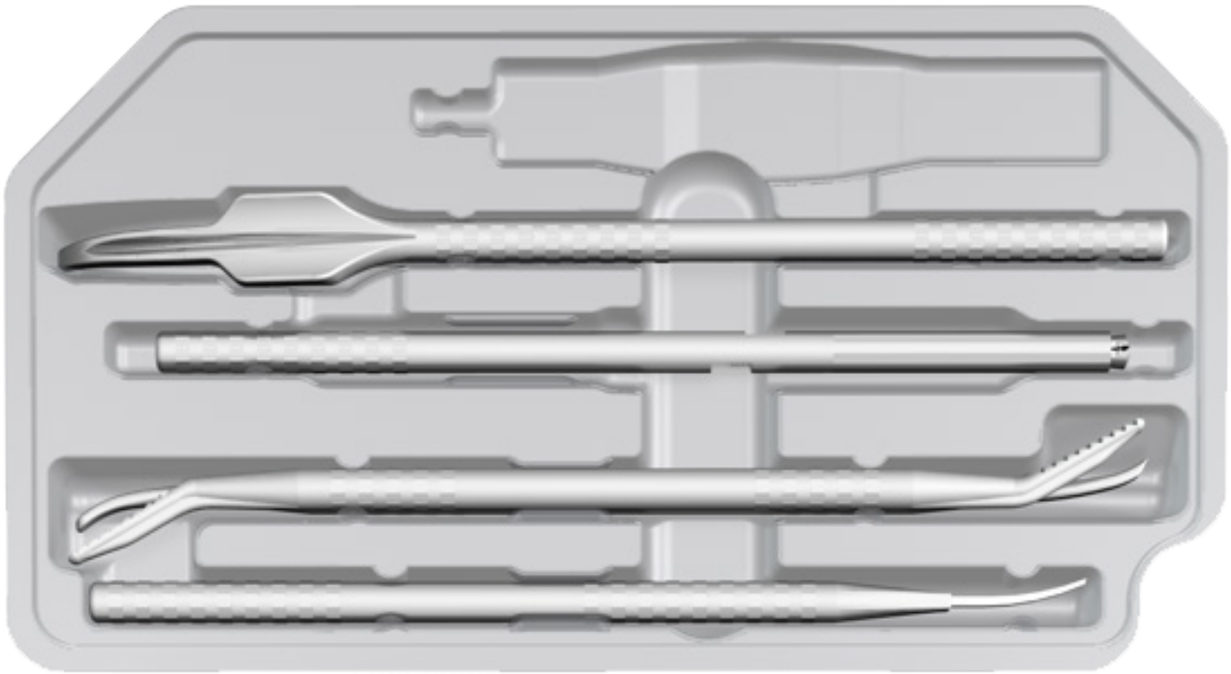
Neomis®

SINGLE USE INSTRUMENT SET



Percutaneous basal metatarsal closing wedge osteotomy
for Hallux Valgus treatment

Surgical technique described by Doctor Christian BAERTICH

In2Bones

A GLOBAL EXTREMITY COMPANY

ST-DIG-NEOMIS-EN-012021

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Indications

The NEOMIS® Single use instruments sets are intended to be used for percutaneous foot surgery.

Warnings and precautions

Physician must determine if the use of the instruments is appropriate for patients who have any of the following conditions:

- Acute or chronic, systemic inflammations,
- Active infections,
- Sensitivity/allergies to the instruments materials (cf label),
- Lacks good general physical condition,
- Use of steroid derivatives, chemotherapy, etc...,
- Drug and/or alcohol and/or smoke addiction and/or abuse,
- Obesity,
- Vascular disorder,
- A patient unwilling or unable to comply with postoperative instructions.

General complications of orthopedic surgery may include, but are not limited to:

- Pain, discomfort or abnormal sensations,
- Wound healing problems,
- Nerve injury,
- Adhesions,
- Infections,
- Hematoma, thrombosis, pulmonary embolism,
- Complications linked to damage or breakage of the instrument.

Percutaneous burrs

Percutaneous burrs are indicated for forefoot mini-invasive and percutaneous surgery.

Shannon burrs are intended to be used for:

- Osteotomy of M1 and/or of P1
- All surgical bone procedures of the lesser toes
- Contouring of metatarsal heads
- The helicoidal design supplies a cut with extraction of bone chips

Wedge burrs are intended to be used for:

- Osteotomy of M1 and/or of P1 (Akin)
- Metatarsal osteotomies
- Cheilectomy of Hallux Rigidus (with the 4,3mm burr)

This design supplies a conical cut with extraction of bone chips.

Neomis®
PRODUCT DESCRIPTION

Instrumentation

NEOMIS® ANS S2012_W39 set is a sterile, single use instrumentation for minimally invasive surgery in the forefoot. Customized to fulfill your specific requirements, the kit contains:

① BEAVER (BLADE HOLDER)

- Hold and lock all geometries of beaver blade
- Blade orientation indication
- Peroperative interchangeability of blade

② SMOOTH ELEVATOR

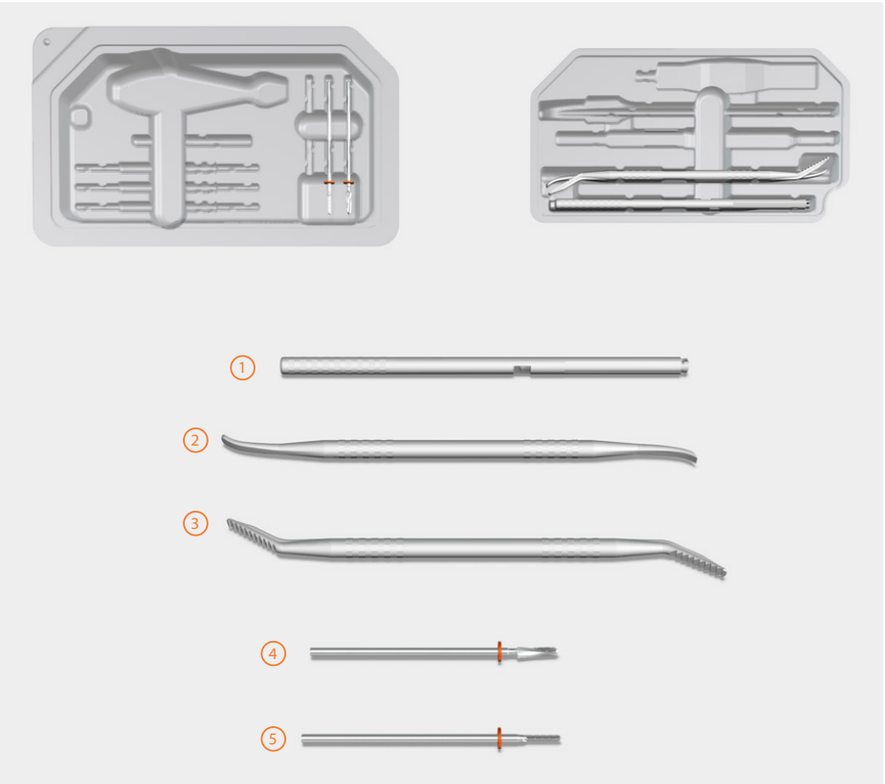
- Separate the soft tissues from bones
- Create a working window

③ REINFORCED BONE DISCHARGER

- The bone discharger is designed to extract small bone debris (and not to rasp the bone)
- Two orientations (angle : 30°) are available
- Anatomic handle for efficient ergonomy

④ WEDGE BURR Ø3.9 length 12.75mm

⑤ SHANNON BURR Ø2.0 length 12mm



Percutaneous burrs for the forefoot surgery

Mini-invasive and percutaneous surgery have similar objectives than open surgery thus reducing the size of the incision.

In2Bones® supplies a range of 8 percutaneous burrs for mini-invasive and percutaneous surgery.

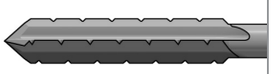
- 2 designs
- Percutaneous burrs are delivered sterile, by pack of 5, or in an individual packaging, each one in an individual double pouch

SHANNON
STRAIGHT BURRS

Straight Cutting Edge

Diam 2 - Lg 12 mm

Diam 2 - Lg 20 mm



Diam 3.1 - Lg 15 mm

Diam 4.1 - Lg 15 mm

Helicoidal Cutting Edge

Diam 2 - Lg 8 mm

Indications:

- Osteotomy of M1 and/ or of P1
- All surgical bone procedures of the lesser toes
- Contouring of metatarsal heads

The helicoidal design supplies a cut with extraction of bone chips

WEDGE
CONICAL BURRS

Diam 2.9 - Lg 13 mm

Diam 3.9 - Lg 12.75 mm

Diam 4.3 - Lg 13 mm

Indications:

- Osteotomy of M1 and/ or of P1 (Akin)
- Metatarsalosteotomies
- Cheilectomy of Hallux Rigidus (with the 4.3mm burr)

This designs supplies a conical cut with exctraction of bone chips

Neomis®
SURGICAL TECHNIQUE

PERCUTANEOUS BASAL METATARSAL CLOSING WEDGE OSTEOTOMY IN THE TREATMENT OF HALLUX VALGUS

Surgical technique described by Doctor Christian BAERTICH

This surgical technique is described using the Neomis® **ANS S2012 W39** kit.

In2Bones® manufacturer of this device does not practice medicine.

It is the responsibility of the surgeon using the medical device to determine and use the most appropriate surgical techniques for each patient. The Surgical Technique Booklet is provided for information purposes, in support of the correct use of the device and the instrumentation dedicated to it.

1 - Patient's position & organization

The patient is placed in supine position, with the foot to be operated protruding from the table to facilitate radioscopic control, with the controlateral knee bent.

2 - Preparation of the articular chamber and exostosectomy

– The initial incision is made at the medial edge of the proximal phalanx of the hallux using the beaver perpendicular, until contact with the medial cortex.

– The beaver is then directed tangentially and penetrates the capsule.

– This gesture should make possible to perform the distal exostosectomy of the first metatarsal and then secondarily, at the end of the surgery, perform a varisation osteotomy of the proximal phalanx of the hallux.

– The smooth elevator is inserted, taking off the capsule, always tangentially and then in a dorsal and plantar sweeping movement to create the joint chamber.

– This gesture must be continued carefully to obtain sufficient working space.

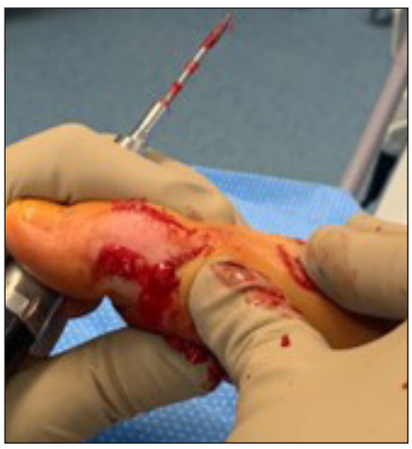
PERCUTANEOUS BASAL METATARSAL CLOSING WEDGE OSTEOTOMY IN THE TREATMENT OF HALLUX VALGUS

Surgical technique described by Doctor Christian BAERTICH

The exostosectomy can begin, using the Shannon 2.0 mm burr. In a first place the burr will complete the capsular detachment and then realize the bone regularization.

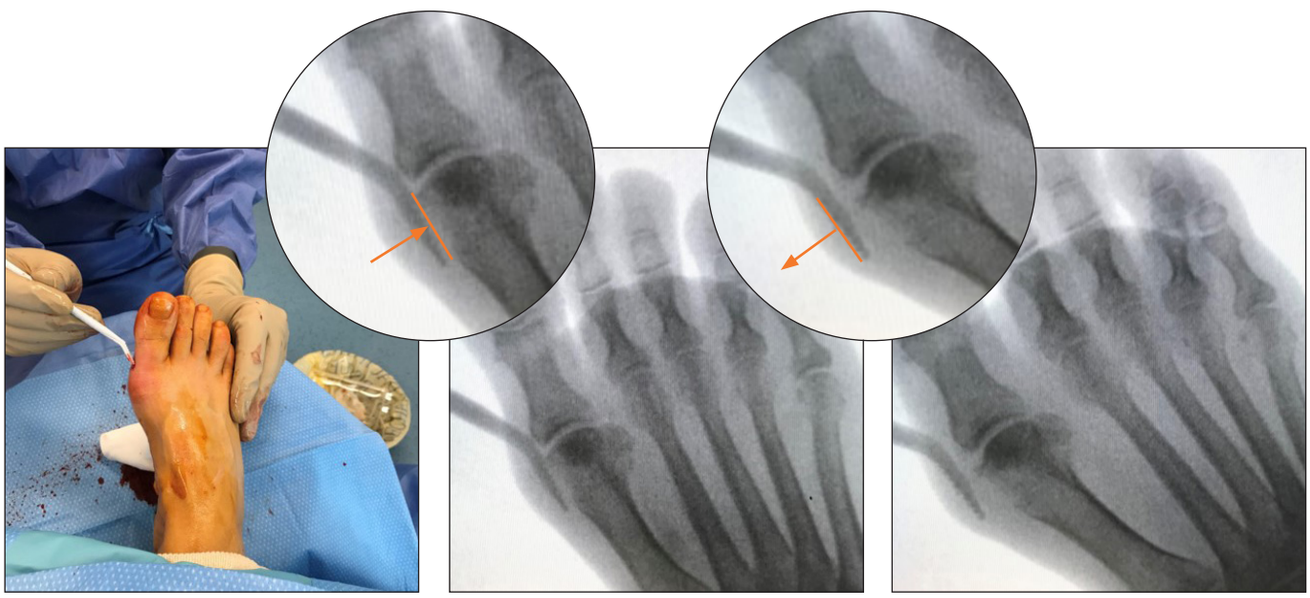
This step is finalized using the Wedge burr of 3.9 mm, to be more aggressive.

At this stage the radioscopic or radiological control is useful in order to control the reality of the exostosectomy and to avoid an overly invasive procedure and excessive aggression of the cartilage surface.



Excess bone and fragments are removed by thumb pressure from proximal to distal.

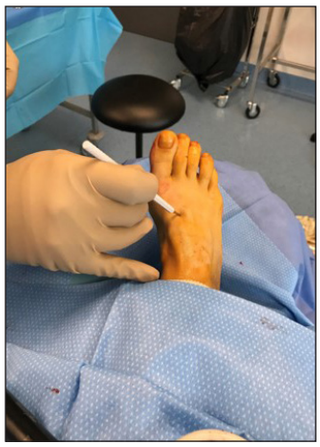
The dual-orientation reinforced bone discharger allows the cleaning of the milled surface and the extraction of the bone fragments from the bone surface and from the capsular inner surface.



PERCUTANEOUS BASAL METATARSAL CLOSING WEDGE OSTEOTOMY IN THE TREATMENT OF HALLUX VALGUS

Surgical technique described by Doctor Christian BAERTICH

3 - Basal osteotomy



The basal osteotomy should be performed in the proximal metaphyseal area at approximately 1 cm from the cuneometatarsal joint.

A too proximal localization can be difficult and may expose to a later articular conflict, a diaphyseal localization leads to a risk of instability and secondary displacement.

The incision is made with the beaver and then the reinforced bone discharger is used to create workspace that protects the soft tissues. The osteotomy area must be prepared, using the smooth elevator, in a vertical movement from dorsal to plantar in order to achieve periosteal detachment.

The 3.9mm Wedge burr is used first to create a bigger working area in a simple translational movement to perform the lateral corticotomy, at the base of the osteotomy site.

Introduce the wedge burr, always in a vertical position, and perform the plantar corticotomy with attention.

Then by raising the hand, the dorsal corticotomy is completed, paying attention not to damage the extensor tendon.

Depending on the metatarsus varus angle, up to half the width of the metatarsal may be cut, but in general, the use of the 3.9 mm Wedge burr is sufficient for 1/3 of this width.

In the same idea the plantar corticotomy can be important if we want to lower the first metatarsal.

The 2.0 mm Shannon burr is vertically positioned and used in a translational movement, up to the medial cortex avoiding fracturing it.

Radiological control is useful during the learning curve period, but progressively the feeling of the tip of the burr in the plantar and medial area, with the index finger of the hand, allows the surgeon to know that the cut is finalized. The objective is to obtain a triangular shape at the end of the procedure.

PERCUTANEOUS BASAL METATARSAL CLOSING WEDGE OSTEOTOMY IN THE TREATMENT OF HALLUX VALGUS

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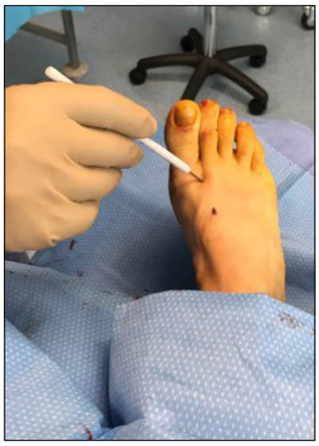
Osteoclasia

The osteoclasia is then performed manually, one hand stabilizing the midfoot, the other hand ensuring by a progressive and gentle movement the closing of the osteotomy.

4 - Lateral release



– The abductor tenotomy is performed using the beaver.

– The beaver is inserted vertically at the contact of the joint capsule, with the sharp side of the blade tangential to the joint capsule in order to preserve the vasculo-nervous system.

– Then in a rotation movement of the hand, placing the sharp side of the blade perpendicular to the capsule, we realize the tenotomy by placing the hallux in forced varus.

It must not be performed with a lateral arthrolysis, which may potentially which may be potentially destabilizing, and could complicate the subsequent closure of the phalangeal osteotomy and could promote an iatrogenic hallux varus

An associated release of the lateral sesamoid can be realized according to the case, allowing a good centering of the sesamoïd band. A small, more proximal incision is then made in order to release the lateral sesamoid suspensory ligament. The radioscopic control is used to check the incision and to correct the beaver position.

5 - Phalangeal osteotomy

- A beaver incision is made at the medial edge of the proximal phalanx, in the metaphyseal-diaphyseal area, corresponding to the proximal 1/3 of the phalanx.
- It is not necessary to perform a periosteal detachment beforehand.
- The 2.0 mm Shannon burr is inserted perpendicularly, drilling the medial cortex and progressing to the lateral cortex limit. It is not achieved bicortically unless there is a rotation disorder to correct.
- The burr is moved back a few millimeters and the dorsal cortical osteotomy is performed, followed by the plantar osteotomy in the same downward movement.
- In order to obtain a triangular section, a few oscillating movements are performed on the medial 2/3 of the osteotomy line, allowing the desired wedge to be created.
- Osteoclasia is performed. It is important to maintain continuity of the lateral cortex, which is a guarantee of stability and good consolidation.

PERCUTANEOUS BASAL METATARSAL CLOSING WEDGE OSTEOTOMY IN THE TREATMENT OF HALLUX VALGUS

Surgical technique described by Doctor Christian BAERTICH

6 - Bandage

This is the last step and it is essential.

A well conducted surgical procedure can be annihilated by a bad bandage. Beforehand, an extensive washing can be performed with physiological serum to eliminate the bone waste.

The incisions are closed with rapid resorption suture (4/0), 2 gauzes are applied to the working areas and the forefoot is wrapped with a Velpeau type bandage from lateral to medial and from dorsal to plantar areas of the forefoot. This circular gesture allows each turn a particular pressure on the head of the first metatarsal, thus stabilizing the closure of the basal osteotomy and the reduction of metatarsus varus.

It can be complemented by the circular application of a plaster*, which acts as a belt. This must be applied without excessive pressure so as not to induce hyper-correction of the metatarsus varus.

This initial step is an important moment for the stabilization of the basal wedge osteotomy.

Bandage - Detail

A gauze folded lengthwise takes the hallux as a scarf, while protecting the medial incision.

The plaster is applied to this gauze on both sides of the hallux:

- At first on the lateral side to close the phalangeal osteotomy.
- In a second step, on the medial side, under the osteotomy in order to reduce the varus and for a better alignment of the metatarsophalangeal joint without opening the osteotomy again.

The finalization of this first step is achieved by the placement of a circular adhesive stripe.

The second and final stage of the bandages are to stabilize reductions and avoid displacement.

PERCUTANEOUS BASAL METATARSAL CLOSING WEDGE OSTEOTOMY IN THE TREATMENT OF HALLUX VALGUS

Surgical technique described by Doctor Christian BAERTICH

6 - Realization of the bandage

A radioscopic control is performed.

In order to avoid a secondary displacement of the basal osteotomy and particularly an elevation of the first metatarsal, a semi-rigid shell is placed on the plantar arch of the foot and stabilized with two strips of plaster.

Finally, a lateral movement from the toes is reduced by the plaster and a syndactyly of the hallux and

of the second toe is performed, always with the aim of improving the stability.

A few turns using a Velpeau type band and a last circular strapped sticky band.







A final radioscopic control is achieved.

7 - Post-Operative Protocol

D15 :

The first bandage is done on the 15th day. it allows to control the good cutaneous healing of the wound incision and the absence of radiological changes. A new bandage is applied, respecting the correct alignment of the 1st ray.




D30 :

On the 30th day, the bandage is permanently removed. A new x-ray control is done.
A comfortable footwear is allowed, with an orthopedic insole to stabilize the arch support of the basal osteotomy and allowing its consolidation as soon as possible. An interdigital orthoplasty is sometimes set up, acting as a guide.

Orthoplasties



PERCUTANEOUS BASAL METATARSAL CLOSING WEDGE OSTEOTOMY IN THE TREATMENT OF HALLUX VALGUS

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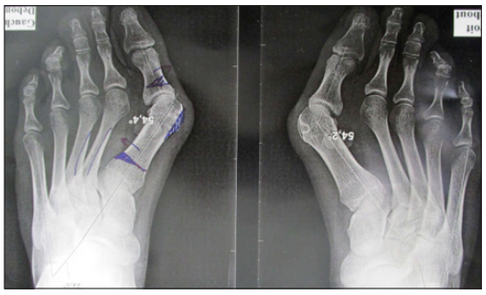
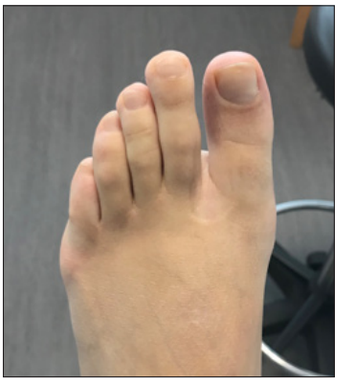
D90 : Clinical and radiological control

New follow-up exam is required to ensure the proper clinical evolution and to check the radiological consolidation of the different osteotomies.

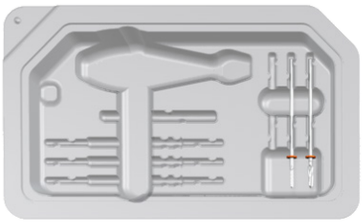


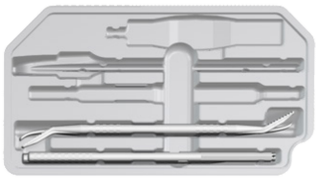
1 year later

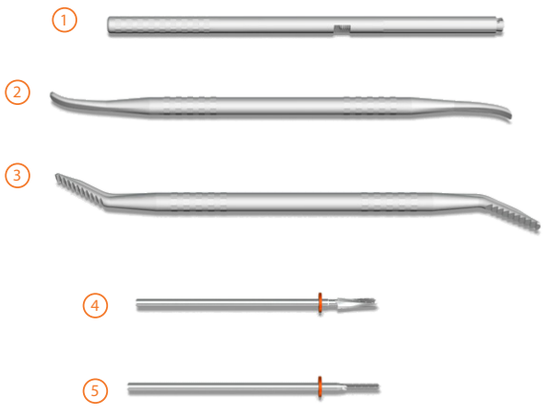
Neomis®
ORDERING INFORMATION

PRODUCTS LIST

Neomis® ANS S2012_W39 Single use instrument set







① BEAVER (BLADE HOLDER)

② SMOOTH ELEVATOR

③ REINFORCED BONE DISCHARGER

④ WEDGE BURR Ø3.9 length 12.75mm

⑤ SHANNON BURR Ø2.0 length 12mm

G01 00961	Pack of 5 wedge burrs lg 13mm - dia 2.9 x longueur 75mm - sterile
G01 01451	Pack of 5 wedge burrs lg 12.75mm - dia 3.9 x longueur 75mm - sterile
G01 00971	Pack of 5 wedge burrs lg 13mm - dia 4.3 x longueur 75mm - sterile
G01 00951	Pack of 5 shannon burrs lg 8mm - dia 2.0 x longueur 75mm - sterile
G01 00941	Pack of 5 shannon burrs lg 12mm - dia 2.0 x longueur 75mm - sterile
G01 01511	Pack of 5 shannon burrs lg 20mm - dia 2.0 x longueur 75mm - sterile
G01 00981	Pack of 5 shannon burrs lg 15mm - dia 3.1 x longueur 75mm - sterile
G01 00991	Pack of 5 shannon burrs lg 15mm - dia 4.1 x longueur 75mm - sterile

Other single-use percutaneous instruments sets are available. For more information please refer to the dedicated brochure.

REGULATORY INFORMATIONS

RECOMMANDATION

It is recommended to carefully read the instructions for use available in the package insert.

DEVICES (CLASSIFICATION PER MDD EC/93/42)

Neomis ANS S2012_W39 Single use instrument set: CE2797 Class IIa
Instruments connected to a power tool: CE2797 - class IIa

REIMBURSEMENT

Reimbursement may vary from countries to countries. Check with local authorities.

MANUFACTURER

In2Bones SAS
28, chemin du Petit Bois
69130 Ecully – FRANCE

Tel : +33 (0)4 72 29 26 26
Fax : +33 (0)4 72 29 26 29

DOCUMENT

Reference : ST-DIG-NEOMIS-EN-012021

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

Always refer to the appropriate instructions for use for complete clinical instructions.

Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.

CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of a physician.

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In2Bones® as the manufacturer of this device, does not practice medicine. The surgeon who performs any implant procedure is responsible for determining and using the appropriate surgical techniques for implanting the device in each patient. This Surgical Technique Manual is furnished for information purposes, as an aid to use properly the device and its dedicated instruments.

International Office
In2Bones SAS • 28, chemin du Petit Bois • 69130 Ecully • FRANCE
+33 (0)4 72 29 26 26 • contact@in2bones.com

Corporate Headquarters
In2Bones Global, Inc. • In2Bones USA • Memphis, TN • USA
+1 844. 602. 6637 • Info@i2b-USA.com