

# unique

## SURGICAL INSTRUMENTS V.3.2

- custom resection guide edition

custom made femoral prosthesis

CE



# Surgical instruments for custom made femoral prosthesis

**IMPORTANT**

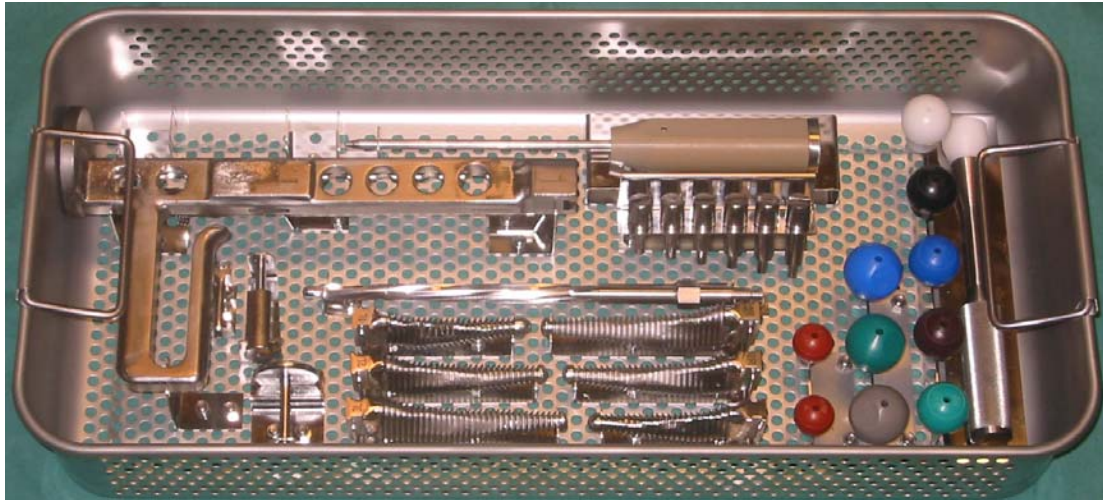
This Instrument Kit should only be used to insert *Unique* customized femoral stems delivered by Scandinavian Customized Prosthesis AS.

Due to special requests from the different orthopedic surgeons, differences between the instruments delivered to the hospital and those described in this manual may occur. For exact content, see inventory delivered with each instrument kit.




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## OVERVIEW OF BASKET









## CONTENT OF BASKET

Object	Illustration	Type/ID.No.
Reamer		Charnley D2354-10
Rasp handle		Rasp Handle-RH RH Main Part: IPO10/IPO69 RH Lifting bracket: IPO11/IPO67 RH Bar: IPO12/IPO62 Spring: Unmarked
Guide pin with end stop		IPO14

Object Illustration Type/ID.No.

<p>Trial tapers</p>		<p>1C: IP103 2C: IP104 3C: IP105 4C: IP106 5C: IP107 6C: IP108</p>
<p>Saw blade</p>		<p>Saw blade with thickness of maximum 0.9mm  Not provided by SCP. May vary according to air tool used in the hospital</p>
<p>Insertion prod for femoral prosthesis</p>		<p>IP015</p>
<p>Set of standard rasps, left side</p>		<p>1L: IP028/IP054/IP099  2L: IP029/IP055/IP100  3L: IP030/IP056/IP101</p>
<p>Set of standard rasps, right side</p>		<p>1R: IP024/IP050/IP095  2R: IP025/IP051/IP096  3R: IP026/IP052/IP097</p>

Object Illustration Type/ID.No.

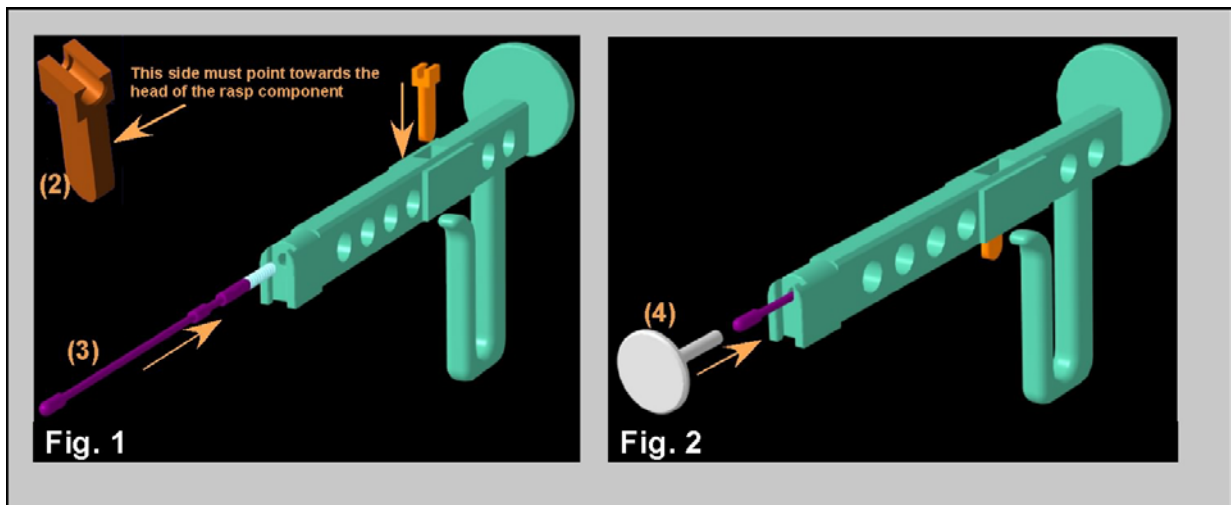
<p>Femoral head impactor</p>		
<p>Trial head 22mm +5 (Neutral position)</p>		
<p>Trial head 22mm +9 (Lengthening of 4.0mm)</p>		
<p>Trial head 28mm S -3.5mm (Shortening of 3.5mm)</p>		
<p>Trial head 28mm M +0mm (Neutral position)</p>		
<p>Trial head 28mm L +3.5mm (Lengthening of 3.5mm)</p>		

<p>Trial head 28mm XL +12mm (Lengthening of 7.0mm)</p>		
<p>Trial head 28mm XXL +15,5mm (Lengthening of 10.5mm)</p>		
<p>Trial head 32mm S -4.0mm (Shortening of 4.0mm)</p>		
<p>Trial head 32 mm M +0mm (Neutral position)</p>		
<p>Trial head 32 mm L +4.0mm (Lengthening of 4.0mm)</p>		

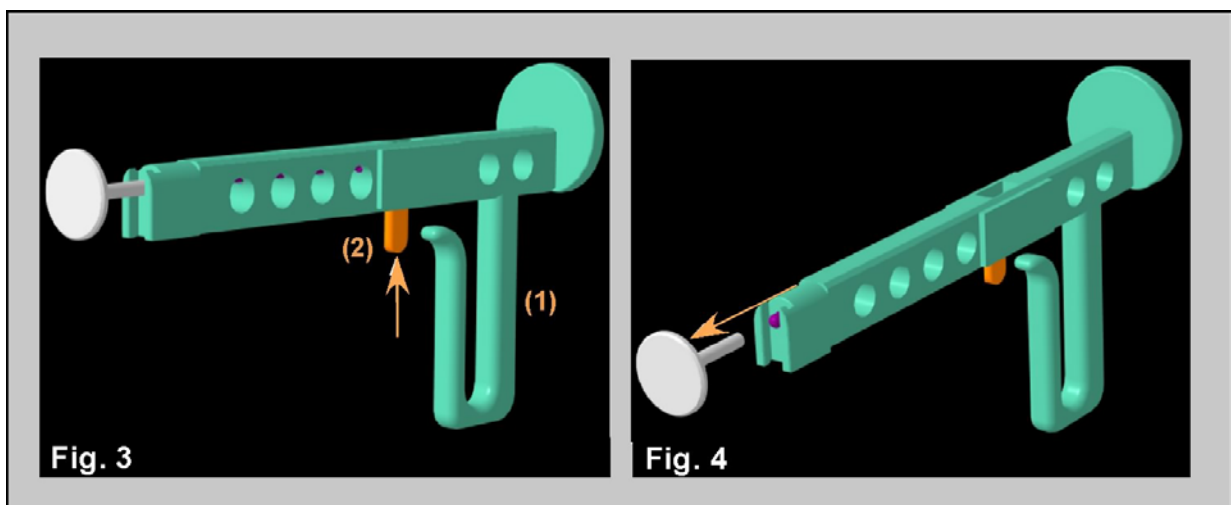
## ASSEMBLIES

### Assembling the rasp handle

- A)** Position the lifting bracket (2) as shown in fig.1 and insert it into the opening on the top of the rasp handle (1).
- B)** Insert the bar with the spring into the hole at the end of the rasp handle (fig. 2).

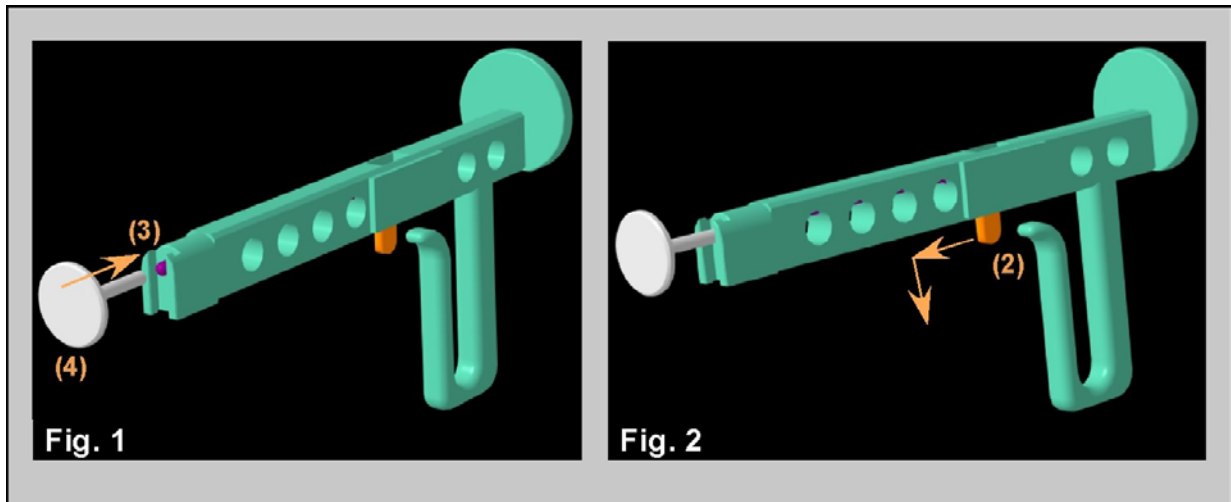


- C)** Use the guide pin (4) to push the bar as far into the hole as possible. Then raise the lifting bracket (2) until it grasps the bar (fig. 3).
- D)** Now remove the guide pin (4) from the hole and the rasp handle is assembled (fig. 4).

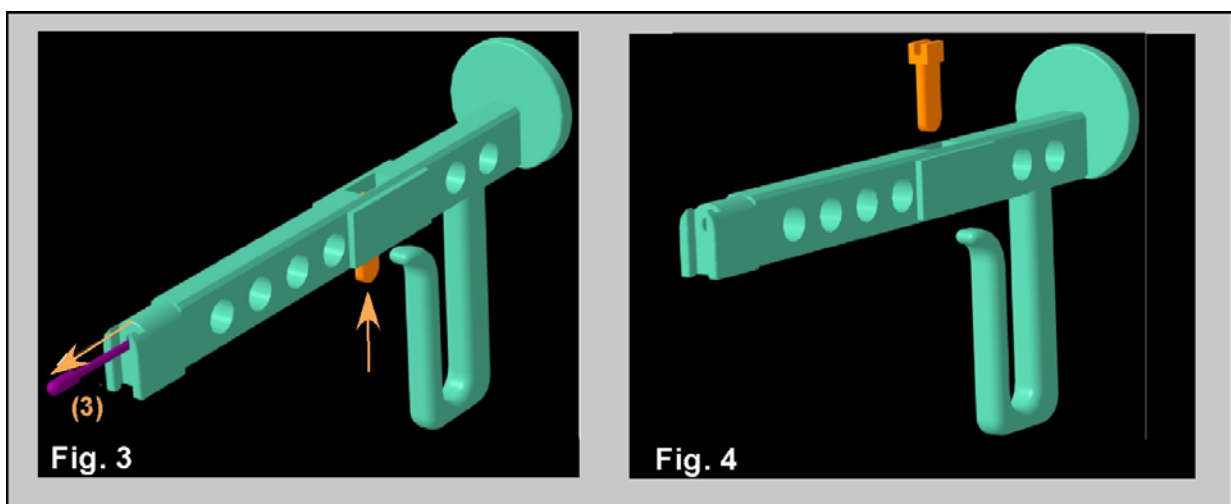


## Dismantling the rasp handle

- A)** Use the guide pin (4) to fully compress the bar with the spring (3) as shown in fig. 1.
- B)** When the bar is fully compressed, push the lifting bracket (2) forward so that it coincides with the thinnest part of the bar (fig. 2).



- C)** Then pull the lifting bracket down and remove the bar with the spring as shown in fig. 3.
- D)** Finally, push the lifting bracket up (fig. 4). The rasp handle is now dismantled.





# WASHING AND STERILIZATION

<b>Products:</b>	Surgical Instrument Set ; Scandinavian Customized Prosthesis ; Norway
<b>ADVICE:</b>	Reprocessing procedures have only limited implications to a surgical instrument. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device.  In case of damage the device should be reprocessed before sending back to the manufacturer for repair.
<b>Reprocessing Instructions</b>	
<b>Preparation at the Point of Use:</b>	Remove gross soiling of the instrument with cold water (<40°C) immediately after use. Clean lumens with a syringe with sterile water. Don't use a fixating detergent or hot water (>40°C) as this can cause the fixation of residua which may influence the result of the reprocessing process. Store the instruments in a humid surrounding.
<b>Transportation:</b>	Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.
<b>Preparation for Decontamination:</b>	The devices must be reprocessed in a disassembled state.
<b>Pre-Cleaning:</b>	Do a manual pre-cleaning with a soft bristol brush, until the instruments are visually clean. Submerge the instruments in an ultrasonic bath with 0,5% alkaline cleaning solution at 40°C for 10 minutes.
<b>Cleaning:</b>	Automated Cleaning:  Put the instuments into the maschine on a tray and start the program <ul style="list-style-type: none"> <li>• 2 min pre-washing with cold water (&lt;40°C);</li> <li>• emptying</li> <li>• 5 min washing with 0,5% alkaline cleaning detergent at 55°C)</li> <li>• emptying</li> <li>• 3 min neutralising with warm water (&gt;40°C);</li> <li>• emptying</li> <li>• 2 min intermediate rinsing with warm water (&gt;40°C)</li> <li>• emptying</li> </ul>
<b>Disinfection:</b>	Automated Disinfection: Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A <sub>0</sub> -Value (see EN 15883)
<b>Drying:</b>	Automated Drying: Drying of outside of instrument through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.
<b>Functional Testing, Maintenance:</b>	Visual inspection for cleanliness of the instruments and reassembling. Functional testing according to instructions of use. If necessary perform reprocessing process again until instruments are visibly clean.
<b>Packaging:</b>	Put the instruments in the Surgical Instrument trays and do an appropriate packaging for sterilization.
<b>Sterilization:</b>	Sterilization of instruments by applying a fractionated pre-vacuum process (according ISO 17665/ under consideration of the respective country requirements.  Minimal requirements: 3 min at 134°C Maximal sterilisation temperature: 138°C  <b>Flash sterilization is not allowed on lumen instruments!</b>
<b>Storage:</b>	Storage according to the hospitals own procedures for handling of sterile equipment.

<p><b>Reprocessing validation study information</b></p>	<p>The following testing test devices, materials &amp; machines have been used in this validation study;</p> <p>Detergent: deconnex 28 Alka One, (Borer, Zuchwil, Switzerland)</p> <p>Washer / Disinfector: Miele G 7735 CD</p> <p>Instrument rack: Miele rack with two layers.</p> <p>Details: See report SMP 02007011402 and SMP 02007022302</p>
<p><b>Additional Instructions:</b></p>	<p>None</p>
<p>It is the duty of the user to ensure that the reprocessing processes including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.</p>	

## PROCEDURE IF ABSENT INSTRUMENTS

1. Every hospital to which Scandinavian Customized Prosthesis as (SCP) supplies *unique* custom made femoral prostheses, need a complete set of instruments, including a pusher and trial heads, for the surgical operation.
2. If any of the instruments are not functioning as specified or damaged during a surgical operation, or if components are missing for any reason, please send a notification to:

Scandinavian Customized Prosthesis as  
Tel. +47 73 40 17 70  
Fax. +47 73 96 31 90  
Contact: Jan Magne Gjerde  
e-mail: jan.magne.gjerde@scp.no

In such cases, SCP must be informed of the serial number (IP number) of the part, which needs to be replaced. If this is not possible, a description of the relevant part must be attempted.

3. The instruments should be serviced regularly. We recommend the following procedure for shipping the instrument kit for service:
  - A) SCP packs a complete set of the instruments and sends it by parcel service to the relevant hospital.
  - B) When the set is received at the hospital, please pack the "old" set in the box immediately, while the parcel service waits, and ship it to SCP.
  - C) The parcel service takes the box containing the "old" set of instruments away. This procedure is to be completed in order to prevent mix-ups between the old and the new set of instruments at the hospital.
  - D) A representative for SCP in the district can also perform the above procedure.

If there are any questions, please do not hesitate to contact SCP.