



INSTRUCTIONS FOR USE

Important

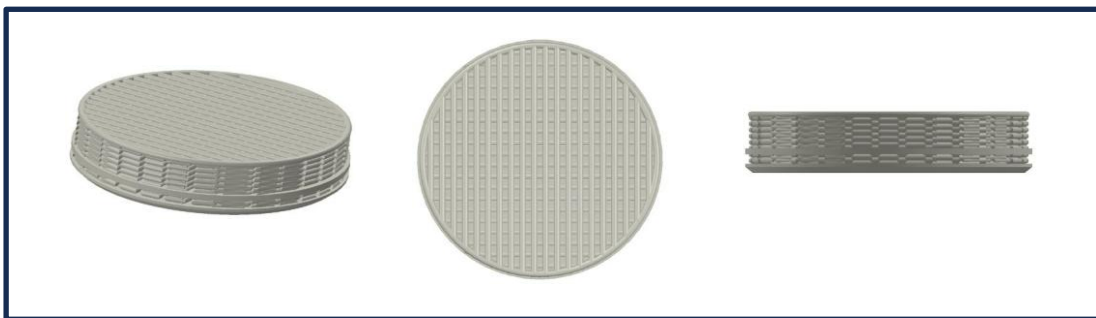
This document provides instructions for use and recommended guidelines exclusively for the **Nanochon Chondrograft™ System** manufactured by Nanochon, Inc. It is important to read this document before using the Nanochon Chondrograft System.

Investigational Device. To be Used by Qualified Investigators Only
Instrument de recherche. Réservé uniquement à l'usage de chercheurs compétents

Description

The Nanochon Chondrograft System consists of the Chondrograft implant (Chondrograft) and Chondrograft instrumentation set. The Chondrograft implant is designed to provide a scaffold for lost or damaged cartilage on the articular surfaces of the knee. The Chondrograft implant is implanted using the Chondrograft instrumentation set. Chondrograft is a porous scaffold made from a proprietary polymer (a composite of Nylon 12 and polyvinyl alcohol (PVA)) and is available in 3 sizes: 10 mm in diameter, 15 mm in diameter, and 20 mm in diameter. All implants are cylindrical in shape and 4 mm thick (*Figure 1*). The Chondrograft implant is packaged in water and should remain hydrated until use.

Figure 1: Chondrograft™ Implant



Investigational Product (IP): Nanochon Chondrograft System which includes:

- Chondrograft implant
- Chondrograft instrumentation set

Intended Use (Indications)

Chondrograft is intended to replace damaged knee articular cartilage with osteoarthritis graded as Kellgren-Lawrence 0-3 having single or multiple chondral or osteochondral defects in the knee.

Contraindications

The Chondrograft implant should not be used under the following conditions or in the following



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patients:

1. Aged < 22 years and ≥ 60
2. Rheumatoid arthritis (RA)
3. Avascular necrosis (AVN)
4. Flexion contracture of >10 degrees
5. Osteoarthritis (OA) Grade IV as defined on radiograph according to the Kellgren-Lawrence Grading
6. Active or latent infection at the surgical site
7. Uncontained lesion without a bone wall surrounding the implantation site
8. Osteochondral or cystic lesions larger than the implant at the implantation site
9. Lesion(s) > ICRS Grade 3C

Use in Specific Populations

- Chondrograft implantation requires a surgical procedure, use in pregnancy is not recommended.
- Not recommended for use in skeletally immature patients.

Implant Care and Sterilization

NOTE: The Chondrograft implant is packaged non-sterile and must be autoclaved before use. The following are recommendations for the sterilization of Chondrograft implant:

Cycle Type	Exposure Time (minutes)	Sterilization Exposure Temperature	Minimum Dry Time*
Prevacuum	4	132°C (270°F)	0

* The implant should remain hydrated and implanted in the hydrated state.

* Dry time should be set to 0 or the shortest allowable time.

* The implant may be immersed in sterile water for injection, while in a sterile surgical field until needed for surgery. It is recommended the implantation occur within two (2) hours of sterilization if possible.

Warnings



WARNING Before using Chondrograft, pay special attention to the warnings below.

- Prior to using Chondrograft, users should be familiar with the proper technique for its use.
- Do not use any part of Chondrograft beyond the indicated expiration date. The performance of the device cannot be assured beyond the expiration date.
- Remove Chondrograft from the package using aseptic technique.
- Chondrograft is packaged in water and fully hydrated.
- Do not let the implant dry out before implantation. Time periods greater than two (2) hours



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may be extended by re-immersion in sterile water for injection after being autoclaved. Chondrograft is intended for one-time use only. After use, or if Chondrograft is opened and not used, dispose of it in accordance with hospital policy and/or local regulations.

- Do not re-sterilize or reuse the implants. Reuse and/or re-sterilization of the device may result in cross- contamination and compromised sterilization. Additionally, these actions may compromise device performance due to inappropriate reprocessing.

Precautions



CAUTION Before using Chondrograft, pay special attention to the warnings below.

Before USE

- A non-intact Chondrograft implant should not be used and should be returned to Nanochon, Inc.
- The plastic tube containing Chondrograft should be inspected prior to opening. If the cap is open, or the container has been damaged, product cleanliness cannot be assured.
- Remove the Chondrograft implant from the plastic tube and place in autoclave tray and sterilize per instructions above. Up to ten (10) implants can be sterilized within the autoclave tray.

During USE

- Procedures are performed either arthroscopically or via mini-arthrotomy
- Confirm Osteoarthritis (OA) Grade $\leq$ IV as defined on radiograph according to the Kellgren-Lawrence Grading
- Care should be used when handling Chondrograft. Ensure clean gloved hands when handling.

The maximum number of implants for a single patient depends on the implant size. The table below provides guidance on implant use per patient.

	Size 20 mm	Size 15 mm	Size 10 mm
Scenario 1	2		
Scenario 2		4	
Scenario 3			8
Scenario 4	1	1	3
Scenario 5		2	4
Scenario 6		1	6

After USE

- To eliminate the risk of possible exposure to blood-borne pathogens, used equipment should be treated in accordance with hospital and safety regulations.
- Guide pins shall be discarded after one usage.



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Adverse Events

- As with all implants, local irritation at the wound site and/or a foreign body response may occur.
- Tissue responses to the implant could include: local infection, inflammation and tissue necrosis. The occurrence of these responses may require surgical removal of Chondrograft.
- Like other implantable devices, Chondrograft or its integration products may potentiate an existing infection.
- Additional surgery related adverse events may include adhesions or arthrofibrosis, chondrolysis, DVT, delayed wound healing, fracture, hematoma, hemarthrosis, joint effusion, range of motions limitation and discomfort, synovitis, tendon injury.
- These events are not necessarily related to Chondrograft and may occur following any cartilage treatment procedure. The above-mentioned adverse events are expected to occur rarely, or with very low frequency. In the event of occurrence, treat per standard of care.

Directions for Use

NOTE: Review the Surgical Technique Guide for complete directions

Nanochon Chondrograft System

The Nanochon Chondrograft System is supplied non-sterile and will be sterilized at the surgical center prior to use. The Nanochon Chondrograft System is comprised of the following components:

- Chondrograft implant
- Chondrograft instrumentation set

The Nanochon Chondrograft instrumentation set is designed to achieve perpendicular orientation of the guide pin, accurate resection depth and reproducible press-fit fixation. The instrumentation set includes the following components:

- Sizing / Alignment Guide
- Punch
- Reamer
- Depth Stop
- Chondrograft Insertion Tube

Note: The Guide pin is single use and will be provided separately.

Surgical Technique

The surgical technique consists of 6 key steps:

1. Implant Size Selection
2. Guide Pin Placement
3. Reaming



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4. Punch the Cartilage
5. Implant Trialing and Guide Pin removal
6. Implant Placement (press fit)

Storage and Handling of the Instrumentation

Instrumentation must be stored and handled with care. Storage must be in a dry, clean location protected from pests and extremes of temperature and humidity. The instruments must not be stored in contact with or near products which may have a corrosive effect.

Sterilization of Instrumentation Set

Note: The Guide Pin is shipped in a separate package from the instrument tray.

All non-sterile instruments are sterilizable by steam autoclave using standard hospital practices, in addition to Nanochon's parameters. In a properly functioning and calibrated steam sterilizer, effective sterilization may be achieved using the parameters prescribed below:

Cycle Type	Exposure Time (minutes)	Sterilization Exposure Temperature	Minimum Dry Time
Prevacuum	4	132°C (270°F)	30

The sterilization parameters identified in this section require the use of a sterilization case wrapped using FDA cleared sterilization wrap. Instruments are to be sterilized within the sterilization case with steam sterilization at a temperature not to exceed 140°C. Consult your sterilization equipment manufacturer's instructions and your internal sterilization procedures for the specific sterilizer and load configuration to be used. The aforementioned sterilization parameters are recommended for the instrumentation including the case. Do not stack cases during sterilization.

Cleaning of Instrumentation

Note: The Guide Pin is single use and shall be discarded once used. This instruction does not apply to cleaning of the Guide Pin.

Instrumentation should be reprocessed as soon as possible after use. If the instrument can be disassembled, disassemble prior to cleaning. Manual cleaning is recommended for the cleaning of the instrument set. Automated washing systems are not recommended as the only cleaning method for the instruments.



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1. Disassemble all instrumentation prior to cleaning, if possible
2. Rinse soiled instrument(s) under cold running tap water for a minimum of two minutes per component.
 - Use a soft bristled brush and/or appropriately sized channel to assist in the removal of gross debris from the external surfaces and internal lumen/cannula surfaces.
3. Soak the instrument(s) for a minimum of fifteen minutes in a neutral pH enzymatic cleaner or detergent solution.
 - Follow the enzymatic cleaner or detergent manufacturer's instructions for water quality, solution preparation temperature and concentration.
4. Rinse the instrument(s) under cold running water for a minimum of two minutes using syringe, pipette, or water jet to clear lumens/cannulas and other hard to clean areas.
5. Manually scrub the instrument(s) using a soft bristled brush for a minimum of five minutes using a freshly prepared neutral pH enzymatic cleaner or detergent solution, prepared according to the manufacturer's instructions.
 - If the instrument(s) can be retracted or moved, retract or open the part to access and clean hard-to-reach areas. Scrub the inside of lumens/cannulas to remove any debris by brushing thoroughly using an appropriately sized, tight fitting soft-bristle channel brush using a twisting action.
 - Using a brush that is too large or small for the diameter of the lumen/cannula may result in an inadequately cleaned surface.
 - Use a firm bristle brush for cleaning bone-cutting features such as rasp teeth.
6. Rinse instrument(s) thoroughly with deionized (DI) or purified water for a minimum of two minutes. Make sure to irrigate the hard to access areas of the instrument(s) .
 - If the instrument(s) can be retracted or moved, it is necessary to retract or open the part for thorough rinsing at these areas. Blind holes should be repeatedly filled and emptied.
7. Visually inspect the instrument(s) under normal lighting for cleanliness. For hard to access areas of the instrument(s), apply a 3% hydrogen peroxide solution.
 - Bubbling indicates the presence of blood and debris. If contamination is present, repeat steps 1 through 7 and reinspect.
8. Prepare an ultrasonic bath with a fresh cleaning solution using a neutral pH enzymatic cleaner or detergent solution at the concentration and temperature recommended by the detergent manufacturer.
9. Immerse instrument(s) completely in the bath and ultrasonically clean for a minimum of fifteen minutes using a minimum frequency of 40 kHz.
10. Perform a final rinse using DI or purified water for a minimum of two minutes.
 - If instrument(s) can be retracted or moved, retract or open the part in order to rinse thoroughly under running water.



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11. Visually inspect the instrument(s) under normal lighting for cleanliness. For hard to access areas of the instrument(s), apply a 3% hydrogen peroxide solution.
 - Bubbling indicates the presence of blood and debris. If contamination is present, repeat steps 1 through 10 and reinspect.
12. Perform a final rinse using DI or purified water for a minimum of two minutes.
13. Dry the instrument(s) using a clean, lint-free cloth or clean compressed air.



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Inspection of the Nanochon Chondrograft System

1. Inspect prior to use. Use normal lighting and no magnification to visually inspect for remaining soil, corrosion, cracks and or for any other damage to the instruments and their components.
2. Check for functionality, up to and including rotating components and actuations.
3. Do not use or discontinue use if the instrument is damaged, malfunctioning or performance is in question.
4. Instruments that are damaged should be reprocessed prior to being returned to the manufacturer for repair.

Storage - Environmental Requirements

Store the Chondrograft implant in a clean, dry area, away from direct sunlight.

Table 1: Symbols Index

Symbol	Description	Symbol	Description
	Catalogue number		Do not re-use
	Do not use if package is damaged		Use by expiry date
	Lot Number/Code		Caution
	Unique device identifier		Manufacturer
	NON STERILE		Do not re-sterilize
	Federal law restricts this device to sale by or on the order of a physician		Medical device
	Consult instructions for use or consult electronic instructions for use		Fragile, handle with care



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