DANIELS

Daniels Medizintechnik GmbH&Co.KG
Pfaffenberger Weg 38
42659 Solingen
Germany

Distributor:

IMT Integral Medizintechnik AG
Haldenstrasse 5
CH-6006 Luzern
Switzerland

Instruction Manual for Air hose

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1. Intended Use

This Air hose has been designed exclusively to connect air driven surgical tools to a medical gas pipeline system.

2. User Qualifications

The use of the Air hose must be carried out by sufficiently qualified and skilled personnel.
Users should report **any serious incident** that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user is established.
These instructions do not explain or discuss clinical procedures.

3. Delivery Condition, Processing and Storage

This Air hose was **not sterilized** before shipment.
Please open the original package and make sure that the Air hose is intact.
Before the first use and immediately after each use the Air hose must be cleaned, disinfected and sterilized. (see chapter 8.)

4. Inspection of the Instrument

Using a not fully-functional Air hose poses an increased Injury and infection control risk.
Always have a spare hose available.
Before each use check the Air hoses intactness, tightness and sufficient air flow with a connected air driver. In case of doubt use a spare hose.

5. Maintenance

The synthetic materials used for this air hose are subject to ageing. The ageing will be accelerated by effect of light and heat, especially by improper cleaning, disinfection and sterilization.
Using an untight or porous Air hose poses an increased injury and infection control risk.

6. Personal Protective Equipment

When using or processing the Air hose always wear appropriate personal protective equipment, e.g. eye wear, face mask, chemical-resistant gloves and moisture-resistant clothing. Blood tissue and infectious materials pose an infection control risk.

7. Use

Use the Air hose only in combination with the intended wall and driver connecting systems.
Make sure the identity of the Air hose according to the imprint on the inlet connector.

To prolong the Air hose only use extension hoses for the specified wall connecting systems.
Only use combinations of Air hoses with maximum 2 hoses and a maximum total length of **800cm**.
The combination of incompatible connecting systems and a too large total length poses an injury and infection control risk.

When using the air hose avoid kinking, squeezing and distorting it.
This causes decreased air flow and will pose an increased injury and infection control risk.
After use detach the quick connector cautiously from the terminal unit.
Sudden pressure drop while detaching the quick connector poses an injury risk for the user.

8. Processing

Before **the first use** and immediately after each use the Air hose must be cleaned, disinfected and sterilized, following the procedures described in this chapter.
For cleaning/disinfection the Air hose must - depending on the combination of inlet and outlet connector - be protected against intrusion of liquids either by connecting the inlet and outlet connector or closing both connectors with a system plug.

8.1 General Basics

In particularly for **the first time use** after delivery, the **non-sterile** hose must be cleaned, disinfected and sterilized, after removal of the transport protective packaging.

Before **each use** the Air hose must be cleaned, disinfected and sterilized.
Effective cleaning and disinfection is an indispensable condition for effective sterilization.

Within the scope on your responsibility for the sterility of the Air hose in use, please make sure that solely sufficient device-specific and product-specific validated procedures will be implemented, used devices (disinfector, sterilizer) will be periodically maintained and tested and the validated parameters will be followed within each cycle.

In addition please note the statutory provisions of your country and the hygiene regulations of the medical practice or hospital.
This applies particularly for the different guidelines for an effective deactivation of prions.

8.2 Cleaning and Disinfection

8.2.1 Basics

As far as possible a machine Procedure (disinfector) should be preferred. A manual procedure – even using an ultrasonic bath – should be applied only if a machine procedure is unavailable, due to notedly lower effectiveness.
The application of a manual cleaning and disinfection procedure must be confirmed by an additional product-specific and procedure-specific Validation under responsibility of the user.
Pre-treatment must be effected in both cases.

8.2.2 Pre-treatment (immediately after use)

First connect the inlet and outlet connector or close both connectors with a system plug depending on what is applicable.
Coil the Air hose slackly with a diameter not less than 25cm.
Coiling is not applicable to spiral shaped Air hoses.
Immediately after use (within maximal 2 hours) visible contamination – if present - must be removed from the Air hoses.

For that purpose use tap water or a disinfectant solution. The disinfectant must be free of aldehyde (otherwise fixation of blood contamination), must possess a proved effectiveness (e.g. DGHM-approval, FDA approval or CE-marking), must be qualified for the disinfection of instruments made of synthetic materials and metals and must be compatible with the Air hoses (see 8.8 resistance of m*aterials*).
For manual removal of contamination only use a soft brush or a soft clean cloth solely dedicated for that purpose, but never metal brushes or steel wool.

Please note, that the disinfectant used within the pre-treatment only serves as operator protection and cannot substitute the subsequently – after passed cleaning – effected disinfection step.

8.2.3 Machine Cleaning/Disinfection

Please make sure within the choice of the disinfector,
- that the disinfector strictly possesses a proved effectiveness (e.g. DGHM-approval, FDA approval or CE-Marking according to DIN EN ISO 15883),
- that as far as possible a proved program for thermal disinfection (not less than 10 minutes at 93 °C or A0-Value > 3000) is available (In case of chemical disinfection risk of disinfectant residues on the air hose),
- that the used program is qualified for the Air hoses and includes a sufficient number of rinse cycles,
- that for closing rinsing only sterile or low-germ (max. 10 germs/ml) and low-endotoxin (max. 0,25 endotoxin units/ml) water (e. g. aqua purificata) will be used,
- that the air used for drying will be filtered and
- that the disinfector will be periodically maintained and tested.

Please make sure within the choice of the detergent system,
- that it is strictly qualified for the cleaning of instruments made of synthetic materials and metals, - that – in case no thermal disinfection is effected – additional a qualified disinfectant with proved effectiveness (e.g. DGHM-approval, FDA approval or CE-marking) has to be used and that the disinfectant must be compatible with the used detergent and that all used chemicals must be compatible with the Air hoses (*see 8.8 Resistance of Materials*). The concentrations specified by the manufacturer of the detergent and, if necessary, disinfectant must be strictly observed.

Workflow:
1. recheck, whether all connectors are tightened properly.
2. place the Air hoses into the disinfector. Make sure that the Air hoses touch each other as few as possible.
3. start the program.
4. remove the Air hoses from the disinfector after the program terminated.
5. prove the Air Hoses und package them immediately after removing from the disinfector (see 8.3, 8.4 and 8.5), if necessary after additional drying at a clean place or machine drying (max. 137 °C).

The evidence of qualification of theAair hoses for effective machine cleaning and disinfection was provided by an independent accredited test laboratory using the disinfector G 7736 (thermal isinfection, Miele & Cie. GmbH & Co., Gütersloh) and the detergent Neodisher medizym (Dr. Weigert GmbH & Co. KG, Hamburg). At this the procedure described above was followed.

8.3 Inspection

Inspect all Air hoses after cleaning respectively cleaning/disinfection on corrosion, damaged surfaces, spalling and visible contamination. Still contaminated Air hoses must be cleaned and disinfected again.

Inspect the Air hoses before sterilization with connected air driver on intactness, tightness and sufficient air flow as well as visible damaging/corrosion. Separate damaged Air hoses.

8.4 Maintenance

As far as possible, lubricants should not be used. If required, only use medical instrument lubricants (white oil) that are qualified for steam sterilization at the maximum sterilization temperature and possess a proved biocompatibility. Avoid direct contact of the lubricants with the synthetic parts of the Air hose.

Please note that the use of unqualified lubricants in conjunction with compressed air poses a fire or explosion risk.

8.5 Packaging

Before sterilization, remove the system plug from the connectors or disconnect the inlet from the outlet connector.
We recommend sterilization in disposable sterilization packaging (single or double packaging) according to the following requirements:
- DIN EN ISO 11607 / ANSI AAMI ISO 11607
- qualified for steam sterilization (temperature resistance at least 141 °C, sufficient steam permeability)

8.6 Sterilization

For sterilization only the following sterilization procedures are applicable; other sterilization procedures are not valid.

Steam sterilization
- fractionated vacuum method (with sufficient drying procedure)
  th*e use of the less effective gravitation method must be validated under the responsibility of the user by an additional product-specific, sterilizer-specific- and procedure-specific validation (possibly longer sterilization time required).*
- steam sterilizer according to DIN EN 13060 / DIN EN 285
- validated according to DIN EN ISO 17665 (former: DIN EN 554 / ANSI AAMI ISO 11134) (valid IQ/OQ (commissioning and product-specific performance assessment))
- maximum sterilization temperature 134 °C (273 °F, plus tolerance according to DIN EN ISO 17665 (former: DIN EN 554 / ANSI AAMI ISO 11134))
- sterilization time at least 20 min at 121 °C (250 °F) or 5 min at 132 °C (270 °F)/134 °C (exposure time while sterilization temperature)

Sterilization with connected system plug or connected inlet and outlet connector is not allowed.

T*he evidence of qualification of the Air hoses for effective steam sterilization was provided by an independent accredited test laboratory using the steam sterilizer EuroSelectomat (MMM Münchener Medizin Mechanik GmbH, Planegg) using the fractionated vacuum method. At this the procedure described above was followed.*

The flash sterilization procedure is strictly not allowed.
Furthermore **do not use** hot air sterilization, irridation sterilization, formaldehyde sterilization, ethylene oxide sterilization or plasma sterilization.

8.7 Storing

Store the Air hose between uses in the sterile package.
To avoid accelerated ageing store the air hose between uses protected against light and heat.

8.8 Resistance of Materials

Please make sure within the choice of the detergents and disinfectants, that the following chemicals are not included:
- alcohols, ketones, esters
- halogenated hydrocarbons
- concentrated acids and bases
- oxidants

Never use metal brushes and steel wool for cleaning.

Never expose the Air hoses to temperatures above 137 °C (279 °F)!**.**

8.9 Reusability

The air hoses can be reused as long as they are undamaged and not leaking.
They must not be reused in cases of discoloration, irreversible deformations, bends or cracks.

Each furthermore reuse or use of damaged or contaminated Air hoses runs under the responsibility of the user.

9. Specifications

Nominal working pressure: **6 bar**
Max. working pressure: **8 bar**