



1504 Grundy's Lane. Bristol PA 19007
Tel: 215-785-1121 - Fax 215-785-1221

January 7, 2003

To: Public Docket: #95D-0349.

Dockets Management Branch (HFA-305)

Food and Drug Administration

5630 Fishers Lane, rm. 1061

Rockville, MD 20852

Reference: SUPAC-IR/MR Equipment Addendum

We would like to be consider for the following:

SUPAC-IR/MR Equipment Addendum: Particle Size Distribution

Nature of the proposed change: Addition of Equipment

Proposed class and subclass of the equipment

Class: Screening Mills

Subclass: Rotating Impeller

Proposed equipment listing: L.B. Bohle

Drawing or picture of the equipment is included

See Description, Brochure.

Sincerely

Rafael Navarro

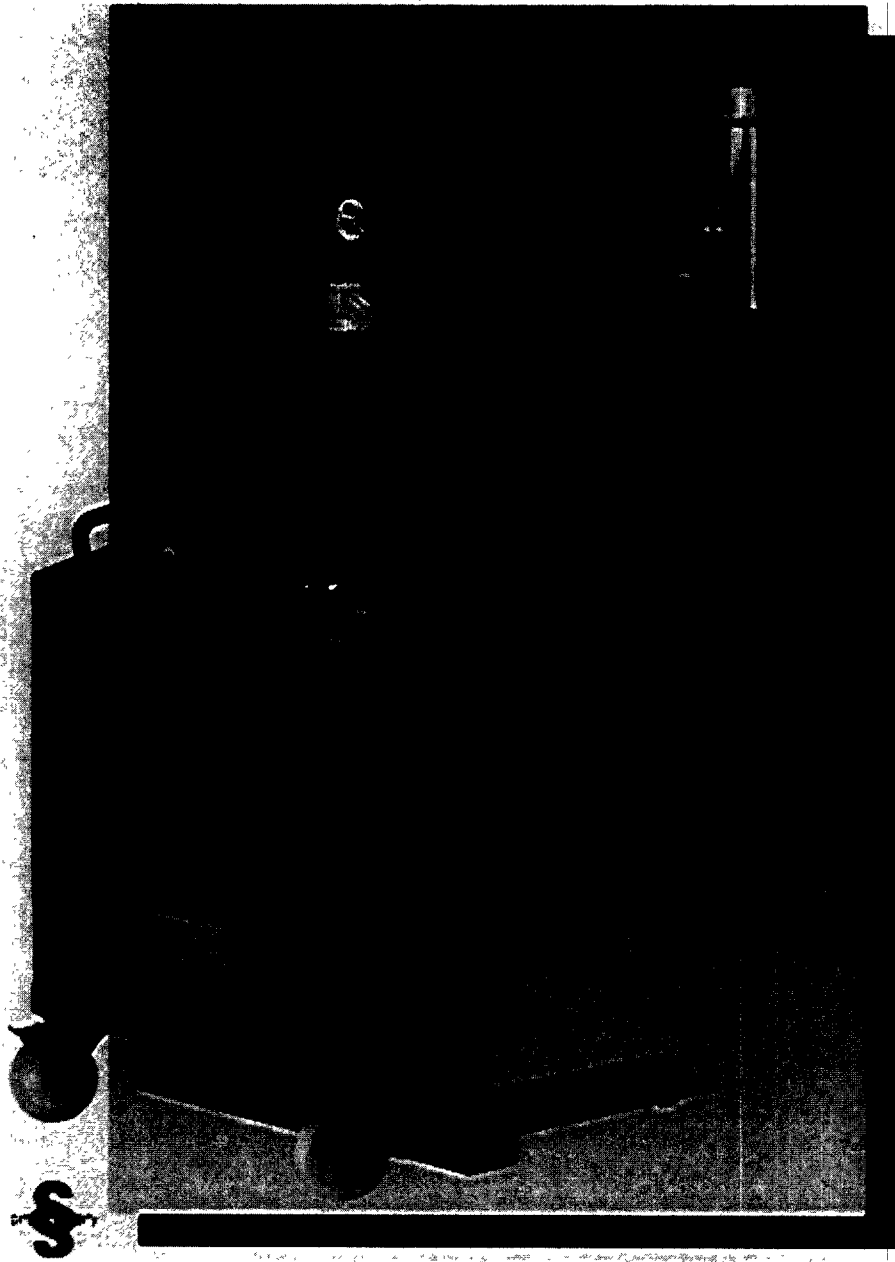
Project Manager

95D-0349

RPT7

LB BOHLE

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BTS-200
Conical Screen Milling System



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Bohle-High-Speed-Mill -BTS 200

Introduction

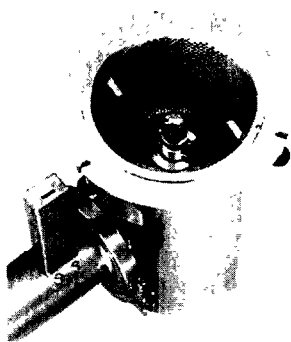
Ten years after the successful introduction of Bohle's low speed milling machine (10 Horse Power) PFG, the line of mills have been expanded with our newly developed high-speed mill BTS 200.

Design

Depending on the application, a variety of screens with different hole patterns / shapes are available. The machine design allows gravity feed through conical shaped screens resulting in high throughput. Two different style impellers are available to match the various applications.

Function

The specially designed impellers will be driven by a shaft drive system resulting in increased throughput at high speeds. Due to the shape of the impellers, downward forces will be applied to the product. The product itself will pass quickly through the screens, reducing stress to the product.



Applications

The BTS can be used in both wet and dry product applications, depending on the application, The right impeller / screen combination has to be chosen and no modifications or adjustments of the BTS are necessary due to the modular design.

Results

Compared to standard mill designs, the new BTS will shorten production times significantly. For example: particularly with low-density materials, throughput was increased by more than 50%.

Handling Advantages

The BTS has been designed to GNP standards, resulting in easy tool-free disassembling for maintenance inspection and cleaning.

For example: after a tri-clamp ring has been removed, the drive system detaches easily, allowing removal of the mill housing (together with impeller and screen). The whole device can now be cleaned in a sterilizer (up to 130° C) without disassembling any single part.

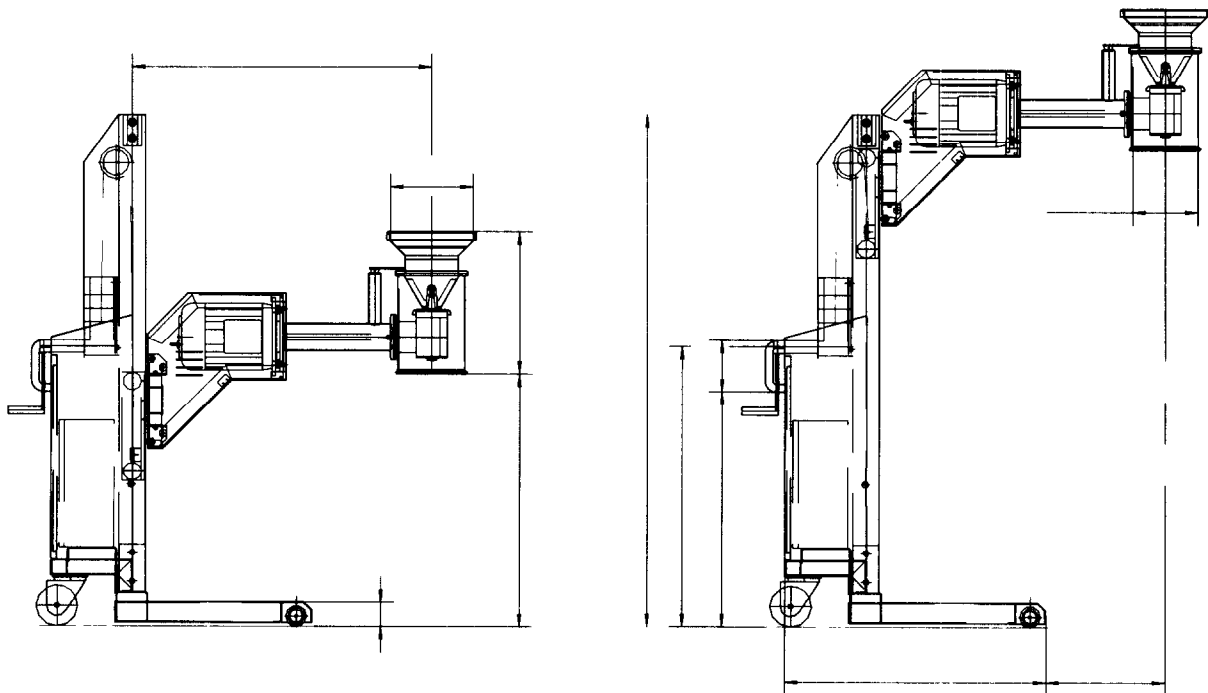
The whole system can be offered for a completely dust-contained application, resulting in minimum product exposure to operators and cleaner production environments.

As standard the BTS will be supplied on a mobile lifter that allows easy height adjustments.

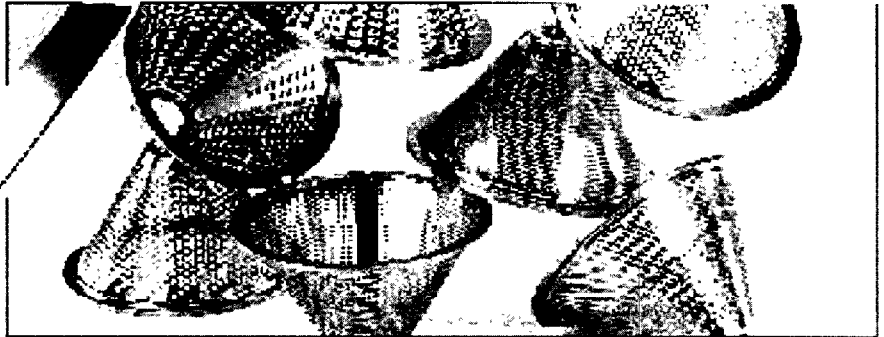
Bohle-High-Speed-Mill BTS 200

- Outstanding performance characteristic, high through-put
- Capable of handling wet and dry products
- Complete milling module can be sterilized at 130° C without disassembling
- Compact GMP design
- Dust-contained design

BTS-200 Standard Drawings



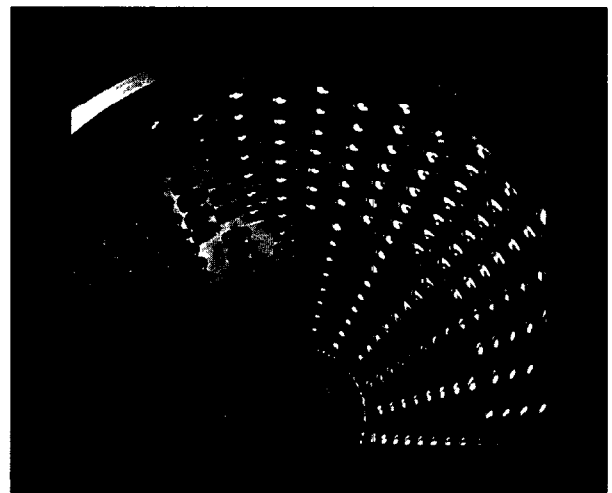
Milling Technology



Grater Type Screen:
Designed for most types of wet &
dry
Applications.

Standard sizes:

1,0 mm	2,0 mm	3,0 mm
4,0 mm	5,0 mm	6,0 mm



Hole Type Screen:
Designed for most types of wet &
dry
Applications.

Standard Sizes:

0,5 mm	1,0mm	1,5 mm
2,0 mm	2,5 mm	3,0 mm



Other screen sizes available as custom designs.

BOHLE

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Patented Bohle Impeller Design, Increases significantly the thru put in comparison to traditional straight bar Impellers design.